

**APPENDIX TO DEFENDANT CSL PLASMA, INC'S  
MOTION FOR SUMMARY JUDGMENT**

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IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
CORPUS CHRISTI DIVISION

MARK SILGUERO,  
Plaintiff,

§ 87(2)(b)

and

AMY WOLFE,  
Intervening Plaintiff,

CIVIL ACTION  
NO. 2:16-CV-00361

V.

CSL PLASMA INC.,  
Defendant.

\*\*\*\*\*

ORAL DEPOSITION OF

NOLA BAKER

June 26, 2017

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ORAL DEPOSITION OF NOLA BAKER, produced as a witness at the instance of the Plaintiff, and duly sworn, was taken in the above-styled and numbered cause on the 26th of June 2017, from 10:34 a.m. to 11:51 a.m., before Isabel Connor, CSR in and for the State of Texas, reported by machine shorthand, at the offices of U.S. Legal Support, Inc., 802 North Carancahua Street, Suite 2280, Corpus Christi, Texas, pursuant to the Federal Rules of Civil Procedure.

Nola Baker  
June 26, 2017

22 to 25

<p style="text-align: right;">Page 22</p> <p>1 A. Yes.</p> <p>2 Q. Where would you document it?</p> <p>3 A. In medical notes.</p> <p>4 Q. If a donor had a complaint about a deferral for</p> <p>5 a medical reason, would you speak with that donor?</p> <p>6 A. No.</p> <p>7 Q. Who would that donor speak to?</p> <p>8 A. If it had to do with a medical deferral that</p> <p>9 they had, they would talk to the medical supervisor.</p> <p>10 Q. Were the -- the medical reception technicians</p> <p>11 trained to refer those complaints to the medical</p> <p>12 supervisor?</p> <p>13 A. Yes.</p> <p>14 Q. Would you ever tell potential donors that they</p> <p>15 were deferred?</p> <p>16 A. Can you repeat that?</p> <p>17 Q. Would you ever tell potential donors that they</p> <p>18 were deferred?</p> <p>19 A. On certain circumstances, yes.</p> <p>20 Q. In what circumstance would you be the one to</p> <p>21 tell potential donors they were deferred?</p> <p>22 A. If they currently had a new tattoo or piercing.</p> <p>23 For example, I -- if I was the one there, I would tell</p> <p>24 them that they were deferred.</p> <p>25 Q. Would you tell them they were deferred if it</p>	<p style="text-align: right;">Page 24</p> <p>1 where it says there's a year deferral.</p> <p>2 Q. When you say that they can dispute it, what do</p> <p>3 you mean by that?</p> <p>4 A. They -- a lot of times donors will try to</p> <p>5 change their -- the information that they gave -- they</p> <p>6 gave you originally, so -- and that's what I mean when</p> <p>7 they would dispute it.</p> <p>8 They would tell -- originally they can</p> <p>9 tell you that they would -- they received the tattoo in</p> <p>10 January of 2017. And then when you're informing them</p> <p>11 that there's a deferral for a year for a tattoo, then</p> <p>12 they try to change their story and change it to January</p> <p>13 of 2016.</p> <p>14 Q. And what if they can prove that the reason for</p> <p>15 deferral was wrong? What if they can prove that they</p> <p>16 made a mistake and, in fact, that really was at the right</p> <p>17 time?</p> <p>18 A. Unfortunately, there's usually no way to prove</p> <p>19 when you got a tattoo. We don't accept any type of</p> <p>20 sterility from facilities to allow the donors to donate.</p> <p>21 It's still a year deferral.</p> <p>22 Q. What reasons do you in your job title typically</p> <p>23 defer people for? You gave the new tattoo or piercing.</p> <p>24 What other reasons do you typically defer people for?</p> <p>25 A. If they have unacceptable behavior, we -- I</p>
<p style="text-align: right;">Page 23</p> <p>1 was for a -- another medical reason, something medical</p> <p>2 that they were being deferred for?</p> <p>3 A. No.</p> <p>4 Q. Who would make that deferral? Who would give</p> <p>5 that deferral notice to the client?</p> <p>6 A. It would be the medical staff or the medical</p> <p>7 supervisor.</p> <p>8 Q. So help me understand. Why would you tell</p> <p>9 someone a deferral for the new tattoo or piercing but not</p> <p>10 for a medical reason? Why did that person come to you,</p> <p>11 but the medical person does not?</p> <p>12 A. The tattoo and piercings are part of the</p> <p>13 medical questionnaire that they answer. And when you're</p> <p>14 screening them in a screening booth, that is something</p> <p>15 that -- the tech would ask them the dates of when they</p> <p>16 received the tattoo and then inform them that there's a</p> <p>17 year deferral for those -- for tattoos or piercings.</p> <p>18 That's outlined for us to be able to tell them.</p> <p>19 Q. And could a potential donor appeal the decision</p> <p>20 of a deferral about a tattoo or piercing?</p> <p>21 A. Can you repeat that?</p> <p>22 Q. Could the potential donor appeal the decision</p> <p>23 of a deferral for a new tattoo or piercing?</p> <p>24 A. They can dispute it, but that is something that</p> <p>25 is outlined. And the procedure is in black and white</p>	<p style="text-align: right;">Page 25</p> <p>1 would defer them.</p> <p>2 Q. What constitutes unacceptable behavior?</p> <p>3 A. When you have a donor that is cussing at your</p> <p>4 employees or throwing something at an employee or try to</p> <p>5 damage your equipment, slamming doors, that sort of</p> <p>6 behavior.</p> <p>7 Q. And are those individuals temporarily deferred</p> <p>8 or permanently deferred?</p> <p>9 A. The -- it depends on the situation. If you --</p> <p>10 if I had a donor that was upset and raised his voice at a</p> <p>11 donor, I would talk to the donor to see exactly what</p> <p>12 happened.</p> <p>13 Normally those donors, when they don't</p> <p>14 cause a big scene like that, are temporarily deferred.</p> <p>15 If you have a donor that is, you know, breaking equipment</p> <p>16 or still -- after I'm talking to them, they are still</p> <p>17 cursing or yelling and threatening, then, yes, they are</p> <p>18 deferred permanently.</p> <p>19 Q. Are there any written policies about deferring</p> <p>20 donors for conduct?</p> <p>21 A. I don't recall.</p> <p>22 Q. Are there any SOPs about donor conduct?</p> <p>23 A. Yes, there is.</p> <p>24 Q. So what it says about donor conduct -- what the</p> <p>25 SOP says about donor conduct?</p>



Nola Baker  
June 26, 2017

30 to 33

<p style="text-align: right;">Page 30</p> <p>1 A. No. There's -- we've had -- I'm trying to 2 think. We had a donor that was deferred for a day for a 3 out-of-range hematocrit. And he did say that he would be 4 waiting outside when we got off from work and he knew 5 what I drove. 6 Q. Did you call the police? 7 A. Yes. 8 Q. Are there protocols about when to call the 9 police? 10 A. Yes. 11 Q. Are those written protocols? 12 A. No. 13 Q. How do you decide whether or not you're going 14 to call the police about a threat? 15 A. Without a threat? 16 Q. About a threat. 17 A. At any time that you feel your life is 18 threatened, we would call the police. Or we feel that 19 anyone in our facility is in danger, we would call the 20 police. 21 Also, if we have a donor that is 22 threatening us and will not leave the building, we would 23 call the police. 24 Q. The donor that you gave an example of taking 25 off his shoe and threatening you with it --</p>	<p style="text-align: right;">Page 32</p> <p>1 Q. When you say you went by what was on the notes, 2 are you referring to what's titled as Exhibit 2? 3 A. Yes. 4 Q. Ever talk to anyone about Mr. Silguero other 5 than Ms. Willing? 6 A. One of the employees, Michelle Mailey, had 7 called me after she was not employed with the company 8 anymore, to ask me questions. She said she was notified 9 that there was a donor that she had deferred. 10 And she wasn't sure what she was supposed 11 to do, because she no longer worked for the company and 12 didn't recall any information. 13 And the only thing I advised her was to 14 talk to whoever was calling her and that they would more 15 than likely give her the information that was noted or 16 that she had noted in the donor's medical notes. And she 17 was the only person other than Ms. Willings. 18 Q. And did she tell you -- did Michelle tell you 19 anything about what she remembered about the donor? 20 A. She didn't -- she didn't mention anything. She 21 was not sure who the donor was. 22 Q. And that she was scared of him? 23 A. She didn't recall who the donor was. 24 Q. And did you tell her anything about what you 25 knew about him?</p>
<p style="text-align: right;">Page 31</p> <p>1 A. Uh-huh. 2 Q. -- did he get deferred? 3 A. Yes, he did. 4 Q. Was he permanently deferred? 5 A. Yes, he was. 6 Q. What about the donor who said that he would be 7 waiting and knew what car you drove, was he permanently 8 deferred? 9 A. Yes, he was. 10 Q. And was there documentation made about these 11 donors' conduct? 12 A. Yes, there was. 13 Q. Where was that documentation made? 14 A. In their medical notes. 15 Q. Do you remember Mr. Silguero? 16 A. I do not. 17 Q. What do you know about this lawsuit? 18 A. I -- the only thing I know is that he's suing 19 the company because he's unable to donate. 20 Q. Do you know why he was unable to donate? 21 A. He made a threatening comment, or he threatened 22 the -- the staff. 23 Q. What was the threat? 24 A. I'm not sure. I went by what was on the 25 medical notes.</p>	<p style="text-align: right;">Page 33</p> <p>1 A. No. I didn't recall who the donor was. 2 Q. When -- when did you have that conversation 3 with her? 4 A. It has been more than eight months ago 5 probably. I don't recall the exact time frame. 6 Q. But you said Michelle was no longer at CSL 7 Plasma when she called you; is that right? 8 A. That's correct. 9 Q. Now, help me understand. Were you Michelle's 10 supervisor at CSL Plasma? 11 A. I was the assistant manager over the -- yes, 12 over those positions. 13 Q. And why do you think that she called you as 14 opposed to one of her other supervisors? 15 A. I -- I couldn't answer that. I'm not sure. 16 Q. Do you feel like you and Michelle were more 17 friendly? 18 A. No, we weren't. 19 Q. Exhibit 2, if you can pull that in front of 20 you, please. I'm going to ask you some questions about 21 it. 22 A. Okay. 23 Q. You see where it says Donor Medical SEQ, S-E-Q, 24 on the second column? 25 A. Okay. Yes.</p>

Joshua Concepcion  
July 06, 2017

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IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
CORPUS CHRISTI DIVISION

MARK SILGUERO,	)	
Plaintiff	)	
	)	
and	)	
	)	
AMY WOLFE.	)	
Intervening Plaintiff	)	
	)	
VS.	)	CIVIL ACTION NO.
	)	2:16-CV-00361
CSL PLASMA INC.,	)	
Defendant	)	

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ORAL DEPOSITION OF  
JOSHUA CONCEPCION  
JULY 6, 2017  
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ORAL DEPOSITION OF JOSHUA CONCEPCION, produced  
as a witness at the instance of DEFENDANT, and duly  
sworn, was taken in the above-styled and numbered cause  
on July 6, 2017, from 1:56 p.m. to 3:25 p.m., before  
Michelle Rodriguez, CSR in and for the State of Texas,  
recorded by machine shorthand, at the offices of 1500  
McGowen, Suite 100, Houston, Texas 77004, pursuant to  
the Texas Rules of Civil Procedure and the provisions  
stated on the record or attached hereto; signature  
having been waived.

JOB NO. 1-HOU-244700

Joshua Concepcion

July 06, 2017

10 to 13

<p style="text-align: right;">Page 10</p> <p>1 e-mail that I would have gotten and then what the 2 changes were.</p> <p>3 Q. So then you were not in charge of making sure 4 the training department implemented the SOP's; is that 5 correct?</p> <p>6 A. No. It would basically just be updating the 7 forms.</p> <p>8 Q. What were your other job duties in the quality 9 department?</p> <p>10 A. It would just be corrective action plans as far 11 as if there was a deviation of some -- some sort in the 12 procedure. So if somebody didn't do an arm scrub -- 13 this was an example -- proper on the donor floor, that 14 could be related to safety. So we would do a track wise 15 which is an investigation of the issue. So why did they 16 deviate from the procedure and just find means to ensure 17 that it doesn't take place again.</p> <p>18 Q. Aside from looking at the donor file, did you 19 do anything else to prepare for today's deposition?</p> <p>20 A. No.</p> <p>21 Q. Who is your supervisor?</p> <p>22 A. It's Stephanie Shah.</p> <p>23 Q. And what is Stephanie Shah's position?</p> <p>24 A. She is the associate director of quality and 25 operations.</p>	<p style="text-align: right;">Page 11</p> <p>1 Q. Does Stephanie have a supervisor?</p> <p>2 A. Yes.</p> <p>3 Q. Who is Stephanie's supervisor?</p> <p>4 A. David Monte.</p> <p>5 Q. Does he oversee more locations than just your 6 location?</p> <p>7 A. Yes. But I think that might be more in 8 Stephanie's scope because they get their own little 9 regions that they cover, and then the RD covers multiple 10 regions. So he has the person under them that would, 11 like, handle my center and so on. So there's, like, 12 clusters I guess I would say.</p> <p>13 Q. So does Stephanie Shah have more than one 14 center that she covers?</p> <p>15 A. Yes.</p> <p>16 Q. Do you handle any of the medical issues that 17 happen at CSL Plasma?</p> <p>18 A. No.</p> <p>19 Q. Do you have knowledge of some of the medical --</p> <p>20 A. I have knowledge of it from when I worked in 21 the quality department.</p> <p>22 Q. What -- what experience did you have on the 23 medical side when you were in the quality department?</p> <p>24 A. That was just mainly, like, the communication 25 aspect between the med staff to the physician because</p>
<p style="text-align: right;">Page 12</p> <p>1 there's forms that they have to complete, reviews that 2 would take place over documentation, ensure that it was 3 accurate -- told a story -- that it was understandable. 4 So it was more so on the lines if there was any errors 5 rather than, I guess, making a decision. It was more 6 review.</p> <p>7 Q. The communication between the medical staff and 8 the physician, what type of communication was that?</p> <p>9 A. There -- there is in-center-visits where they 10 come in, and they have meetings. They do the 11 communication where it's over the phone, and that's when 12 they would generate -- it's called an MCF, so it's a 13 medical communication form. So that would just 14 basically be able to document what took place as far as 15 decisions being made, what was being asked, so on and so 16 forth.</p> <p>17 Q. Does the MCF become part of the donor file?</p> <p>18 A. Yes.</p> <p>19 Q. Did you look at an MCF in preparation for this 20 case?</p> <p>21 A. No, I -- oh, wait. Yes. I'm sorry. I 22 apologize, yes.</p> <p>23 Q. In any position that you had at CSL Plasma, did 24 you ever participate in any sort of Americans with 25 Disabilities Act or ADA training?</p>	<p style="text-align: right;">Page 13</p> <p>1 A. No.</p> <p>2 Q. Have you ever had any training about disability 3 discrimination?</p> <p>4 A. No. It's just that the only experience I 5 really had with the ADA is more so on, like, the 6 employee aspect. So if there was issues related to 7 where they would need, like, accommodations so on and so 8 forth, I would go through HR. And HR would give, like, 9 the guidance as far as this is -- I would tell the 10 situation. This is what it is, and this is what would 11 be the appropriate action. I haven't had the example 12 yet take place, but that's kind of what the -- the 13 training, I guess I would say, was told to me if there 14 was something that needed to be handled. I would just 15 go through the human resources department.</p> <p>16 Q. Would an employee be in charge or -- I'm sorry. 17 Would an employee go to you if they had a 18 need for an accommodation?</p> <p>19 A. It would -- it would be myself and other -- I 20 have assistant managers, as well. So it would be any 21 one of us, yeah.</p> <p>22 Q. Do you know if any CSL Plasma employees 23 received training on the ADA?</p> <p>24 A. Not to my knowledge.</p> <p>25 Q. Did you ever receive any training about how to</p>

Joshua Concepcion

July 06, 2017

22 to 25

<p style="text-align: right;">Page 22</p> <p>1 honestly, that the MSA's could reach out to if they were  2 unable to reach the physician that's for our center.  3 COURT REPORTER: For the, what? I'm sorry.  4 THE WITNESS: For our center. Sorry.  5 COURT REPORTER: Oh, "for our center."  6 Q. (BY MS. DAVIS) And who answers the phone at  7 the Med-Ops hotline?  8 A. It's whoever is on duty at that time. I  9 wouldn't know.  10 Q. Is it a physician?  11 A. I honestly don't know.  12 Q. Do you ever have reason to call the Med-Ops  13 hotline?  14 A. No.  15 Q. Are you ever the one to tell potential donors  16 if they are deferred?  17 A. Yeah. I -- based on, like I said, situational.  18 It would be based on the situation. I have told donors  19 that they're deferred.  20 Q. In what situation have you told donors that  21 they are deferred?  22 A. Basically -- mainly, it's behavior. Behavior,  23 complaints basically all due from behavior or if they're  24 already deferred, like I said, due to, like, a vital  25 situation or they, you know, that's really it.</p>	<p style="text-align: right;">Page 23</p> <p>1 Q. Are there other times that you would tell  2 donors that they're deferred?  3 A. I haven't -- I haven't experienced it yet. I  4 would imagine maybe in the future.  5 Q. In vital situations, you might be the one to  6 tell them that they're deferred?  7 A. I would basically just reiterate what was  8 already told to them by either a tech or if they talked  9 to an MSA first. But normally that doesn't happen  10 because the techs can tell them, "Hey, your deferred  11 based off of -- you don't meet the criteria." So if  12 they then want to speak to a manager right away, then  13 they'll talk to me. So realistically, it's just after  14 the tech.  15 Q. What happens after someone gets deferred?  16 A. Based on, what scenario? Because there's  17 multiple reasons why they would get deferred.  18 Q. What happens in a scenario in which someone is  19 deferred for conduct?  20 A. Conduct? Oh, okay. So if they -- before  21 donate -- I'll just use an example if they haven't  22 donated yet. Say, if they're in a reception area, and  23 they're being loud and disruptive. So, like, talking  24 and being rude amongst each other and it's being  25 disruptive to everybody around them, of course, one of</p>
<p style="text-align: right;">Page 24</p> <p>1 the staff members or somebody would say, "Hey, can you  2 keep it down?" And then if it doesn't end well, it's --  3 or, "F-you," or whatever the situation may be, then of  4 course that's when they would be pulled to the side, be  5 counselled, and they would call me. I would have to  6 talk to them.  7 So that would be the reason that we could  8 defer them if they wouldn't calm down which has happened  9 before. So if they don't calm down, they would be  10 deferred for either the day or depending on the  11 situation if they got violent.  12 Q. And if they're violent, they become a permanent  13 deferral?  14 A. Yes?  15 Q. And if it is just bad language or being angry,  16 is that a permanent deferral?  17 A. It's -- it's basically based on the situation.  18 It's hard to really say. Like, if somebody is being  19 super aggressive and threatening bodily harm, then, of  20 course, that would be a permanent deferral. But if it's  21 just, like, an "F-you" or they said something on their  22 way out, then it would just be a deferral for that day  23 until they came back to be counselled.  24 Q. And who makes that decision?  25 A. It could be myself. It could be one of the</p>	<p style="text-align: right;">Page 25</p> <p>1 assistant managers. It could be a center supervisor.  2 That's the ones that make the call for behavior. As far  3 as vitals, that's strictly from an SOP and from the  4 techs.  5 Q. Can a medical staff associate make a decision  6 about behavior?  7 A. No, they don't -- they don't do that.  8 Q. Could a potential donor disagree or complain  9 about the reason for deferral?  10 A. Yes.  11 Q. Who would they complain to?  12 A. They would come to me, more than likely, if I  13 was there.  14 Q. And would you ever have a reason to then call  15 someone above you about that deferral?  16 A. It's just depending if -- if I couldn't make a  17 judgment call or I didn't seem -- like, if I had to  18 refer to SOP and just didn't feel comfortable making a  19 decision, then, yeah, I could call -- reach out to my  20 boss and say, "This is the scenario. How would you want  21 me to proceed or how should I proceed?" But I haven't  22 done that yet. So --  23 Q. You said you would have to refer to an SOP,  24 potentially?  25 A. If it was related to a -- to something then I</p>

Joshua Concepcion  
July 06, 2017

30 to 33

<p style="text-align: right;">Page 30</p> <p>1 A. -- sounding last name.</p> <p>2 Q. I called them the same name.</p> <p>3 If Oscar Beasley or Sharon Easley were at</p> <p>4 the center in October of 2016?</p> <p>5 A. Oscar Beasley was. I'm not 100 percent for</p> <p>6 Sharon because she was a transfer from another location,</p> <p>7 so I don't remember exactly what her start date was.</p> <p>8 Q. Do you remember Ms. Wolf?</p> <p>9 A. No, I don't remember.</p> <p>10 Q. Did you ever hear anybody talk about her?</p> <p>11 A. No.</p> <p>12 Q. And did you ever talk to anybody about her</p> <p>13 aside from Ms. Willing?</p> <p>14 A. No.</p> <p>15 Q. Do you know why the recommendation was to defer</p> <p>16 Ms. Wolf?</p> <p>17 A. Based on what I saw, the information today,</p> <p>18 from my understanding it was due to the anxiety of the</p> <p>19 -- high level anxiety. That's from what I gather.</p> <p>20 Q. And why is somebody with anxiety not allowed to</p> <p>21 donate?</p> <p>22 A. Just from pure logical reasoning. I would say</p> <p>23 that it was maybe due to the fact that the setting, as</p> <p>24 far as the large needle being placed into their arm.</p> <p>25 And depending on what, you know, heightens their</p>	<p style="text-align: right;">Page 31</p> <p>1 anxiety. There's just a lot surrounding it. So I -- it</p> <p>2 could be a safety risk for them and also others around</p> <p>3 them.</p> <p>4 Q. Has anybody with anxiety ever donated?</p> <p>5 A. I haven't -- I don't know, honestly, offhand.</p> <p>6 Q. Have you ever had a donor have a bad reaction</p> <p>7 to donation?</p> <p>8 A. Yes.</p> <p>9 Q. What happened?</p> <p>10 A. Just pallor which is sweating, diaphoresis --</p> <p>11 diaphoresis and then, you know, discomfort, sweating,</p> <p>12 loss of consciousness, emesis.</p> <p>13 Q. Were they deferred after they had that bad</p> <p>14 reaction?</p> <p>15 A. It just depends on the -- the scenario based</p> <p>16 off the MSA's evaluation and the physician's evaluation.</p> <p>17 It varies from donor to donor on severity.</p> <p>18 Q. Do MSA's have wide latitude to make decisions</p> <p>19 about the judgment or make decisions about the client</p> <p>20 and the donation of the client?</p> <p>21 A. As far as from a medical standpoint?</p> <p>22 Q. Yes.</p> <p>23 A. Yes.</p> <p>24 Q. Has a donor ever appeared anxious?</p> <p>25 A. Not that I can think of, no.</p>
<p style="text-align: right;">Page 32</p> <p>1 Q. Is it possible that someone who did not report</p> <p>2 anxiety could still get anxious during the donation</p> <p>3 process?</p> <p>4 A. That's possible. I would assume that's</p> <p>5 possible.</p> <p>6 Q. And is it possible that somebody with anxiety</p> <p>7 could still donate without any issue?</p> <p>8 A. Possibly. I -- I can't say because I don't --</p> <p>9 I don't know. But if they don't disclose their medical</p> <p>10 history then that would be a reason.</p> <p>11 Q. Has anybody ever had an anxiety attack on the</p> <p>12 donor floor that you know of?</p> <p>13 A. Not that I know of. It's -- it's mainly the</p> <p>14 symptoms that I said.</p> <p>15 Q. Do you have any reason to believe that Ms. Wolf</p> <p>16 does not have a disability?</p> <p>17 A. Well, I just met her right now. I wouldn't --</p> <p>18 wouldn't know. I don't know. I see a service dog, but</p> <p>19 I don't -- like, as far as the anxiety -- that's from</p> <p>20 what I would gather. So --</p> <p>21 Q. So any reason to believe that she doesn't have</p> <p>22 a disability? Any reason why you do believe she does</p> <p>23 not have a disability?</p> <p>24 A. I wouldn't know. I don't -- that's a</p> <p>25 hard answer -- I mean, question for me to answer. I</p>	<p style="text-align: right;">Page 33</p> <p>1 don't know her outside of just meeting her right now.</p> <p>2 Q. Any reason to believe that Ms. Wolf's service</p> <p>3 animal is not a service animal?</p> <p>4 A. No.</p> <p>5 Q. Any reason to believe that Ms. Wolf does not</p> <p>6 get a benefit from having a service animal?</p> <p>7 A. Not that I'm aware of, no.</p> <p>8 Q. I want to look at Exhibit 5 again. You have it</p> <p>9 in front of you still.</p> <p>10 A. (Indicating.)</p> <p>11 Q. On the first page, page 1 of 73, do you see</p> <p>12 that?</p> <p>13 A. Yes.</p> <p>14 Q. The second paragraph it indicates, "This does</p> <p>15 not apply to those labeled regulatory requirement." Do</p> <p>16 you know what the regulatory requirement is?</p> <p>17 A. Not offhand, no.</p> <p>18 Q. Do you know how you would be able to find out</p> <p>19 or where you would look to find out what the regulatory</p> <p>20 requirement is?</p> <p>21 A. I would just reach out to either somebody in my</p> <p>22 quality department or, again, my ADOQ if I had questions</p> <p>23 regarding something I didn't understand.</p> <p>24 Q. What other job duties does the quality</p> <p>25 department have?</p>



Joshua Concepcion

July 06, 2017

42 to 45

<p style="text-align: right;">Page 42</p> <p>1 He just really kind of wanted to be heard.</p> <p>2 Q. Was he angry?</p> <p>3 A. He seemed upset.</p> <p>4 Q. And had he asked the staff that he wanted to</p> <p>5 talk to with the staff supervisor?</p> <p>6 A. Yeah.</p> <p>7 Q. And you mentioned earlier that you've received</p> <p>8 threats; is that right?</p> <p>9 A. Well, everybody kind of receives some sort of,</p> <p>10 you know, "I'll kick your -- you know -- butt," or</p> <p>11 whatever the case may be. But I don't remember them all</p> <p>12 right offhand. But, yeah, we've all received some sort</p> <p>13 of bodily harm or threat at some point in our career.</p> <p>14 Q. A threat of physical violence?</p> <p>15 A. Yeah.</p> <p>16 Q. Has anybody ever threatened to go to a</p> <p>17 supervisor or to go above you?</p> <p>18 A. Yes.</p> <p>19 Q. Has anybody ever said that, "You'll be sorry,"</p> <p>20 once they go to the supervisor?</p> <p>21 A. Yeah, I would assume so. Yeah. I would say,</p> <p>22 yes, because, like, I've heard it kind of all. So,</p> <p>23 yeah. I would say that happened, yes.</p> <p>24 Q. And if somebody told you, "You'll be sorry,"</p> <p>25 how would you interpret that?</p>	<p style="text-align: right;">Page 43</p> <p>1 A. Well, depending on how they say it or how</p> <p>2 aggressive -- how aggressive they were, I would think it</p> <p>3 was kind of a threat. It would be threatening as far</p> <p>4 as, like I said, situational on how they said it. Were</p> <p>5 they aggressive when they were saying it, flailing their</p> <p>6 arms, you know, it's just all situational. So -- but I</p> <p>7 would take it as a threat.</p> <p>8 Q. So if somebody said, "You'll be sorry," could</p> <p>9 it mean that they were threatening to go to your</p> <p>10 supervisor?</p> <p>11 A. They could. Like I said, it's just -- it's</p> <p>12 based on situation. So if they were calm and had a calm</p> <p>13 demeanor and they said that, then I would just think</p> <p>14 that they would think I would get in trouble or get</p> <p>15 fired or whatever their mindset would have been when</p> <p>16 they said it.</p> <p>17 Q. And you'd be sorry because you got fired?</p> <p>18 A. Yeah.</p> <p>19 Q. Or you'd be sorry because you got in trouble?</p> <p>20 A. Reprimanded -- reprimanded of some sort.</p> <p>21 Q. Have you ever been reprimanded because of a</p> <p>22 donor complained about you or your conduct?</p> <p>23 A. No.</p> <p>24 Q. Are you in charge of reprimanding staff members</p> <p>25 who get -- are complained about by donors?</p>
<p style="text-align: right;">Page 44</p> <p>1 A. Yes.</p> <p>2 Q. And when was the last time that you reprimanded</p> <p>3 a staff member?</p> <p>4 A. Probably less than a week ago.</p> <p>5 Q. And what was that about?</p> <p>6 A. I guess the -- well, not guess. What happened</p> <p>7 was, the -- the donor -- excuse me -- had to use the</p> <p>8 restroom. And he actually wasn't able to hold it until</p> <p>9 the restroom, so he went on himself before they could</p> <p>10 take the needle out. And the staff member just wasn't</p> <p>11 as professional as she should have been as far as</p> <p>12 handling the situation. So I had to counsel her. The</p> <p>13 donor actually didn't complain. I just saw it happen,</p> <p>14 and that's when I had to reprimand her and then did a</p> <p>15 corrective action with her as far as her</p> <p>16 professionalism. So -- but that's -- as far as that,</p> <p>17 that's the only thing that comes to mind.</p> <p>18 Q. And the donor didn't -- wasn't the one that</p> <p>19 complained to you?</p> <p>20 A. No.</p> <p>21 Q. It was something that you observed?</p> <p>22 A. (Indicating.)</p> <p>23 Q. And you observed it because you were on the</p> <p>24 floor?</p> <p>25 A. Walking through.</p>	<p style="text-align: right;">Page 45</p> <p>1 MS. DAVIS: Okay. Those are all the</p> <p>2 questions. We can go off the record.</p> <p>3 (Proceedings concluded at 3:25 p.m.)</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>



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10 to 13

<p style="text-align: right;">Page 10</p> <p>1 A. Matter of who was available, yes.</p> <p>2 Q. So it wasn't a matter of what type of questions</p> <p>3 she had; is that right?</p> <p>4 A. Yes.</p> <p>5 Q. And how did she know that she was supposed to</p> <p>6 go to you or Rey with questions?</p> <p>7 A. What do you mean?</p> <p>8 Q. How did she know that you or Rey were the</p> <p>9 people to go to with questions?</p> <p>10 A. That's how she was advised.</p> <p>11 Q. Okay. So it was part of her training?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. And did you train her on when -- when</p> <p>14 she was supposed to go to you or Rey with questions, like</p> <p>15 what types of scenarios prompted her to go to you or Rey?</p> <p>16 A. With any scenario we always go to our medical</p> <p>17 staff reference. That is our go-to. If she still had a</p> <p>18 question, she could either go to me or her -- to me,</p> <p>19 to -- or Rey.</p> <p>20 Q. Okay. So her first step was to look at the</p> <p>21 medical staff reference; is that right?</p> <p>22 A. Yes, ma'am.</p> <p>23 Q. And if the medical staff reference didn't</p> <p>24 ask -- answer her question, her second step would be to</p> <p>25 go to you or Rey; is that right?</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. What is this document?</p> <p>2 A. This is our document for any condition that we</p> <p>3 come upon. Any question that we have, we go and refer to</p> <p>4 it.</p> <p>5 Q. How frequently do you refer to this document?</p> <p>6 A. Just depending on the day, the situation.</p> <p>7 There's no exact times we go back and reference it.</p> <p>8 Q. Are you supposed to look at it with every</p> <p>9 client -- or every donor?</p> <p>10 A. If there's need to, yes.</p> <p>11 Q. So if there's need to refer to the conditions</p> <p>12 guidelines, you are supposed to look at it; is that</p> <p>13 right?</p> <p>14 A. Yes.</p> <p>15 Q. Were you trained on these guidelines?</p> <p>16 A. Yes.</p> <p>17 Q. Who trained you?</p> <p>18 A. Noemi. I don't remember her last name.</p> <p>19 Q. And when was that?</p> <p>20 A. I can't recall at this time.</p> <p>21 Q. Was it when you first started?</p> <p>22 A. Oh, yes.</p> <p>23 Q. So is it fair to say that it was around</p> <p>24 December 2012?</p> <p>25 A. Yes -- well, the first month or two. I was</p>
<p style="text-align: right;">Page 11</p> <p>1 A. Yes.</p> <p>2 Q. Were there times that you or Rey wouldn't know</p> <p>3 the answer?</p> <p>4 A. Yeah. There would be times we wouldn't know,</p> <p>5 and we would ask her to contact our center physician.</p> <p>6 Q. And did you and Rey hold the same job title?</p> <p>7 A. No.</p> <p>8 Q. Because your job title was just MSA; is that</p> <p>9 right?</p> <p>10 A. Yes.</p> <p>11 Q. How frequent was it that MSAs came to you -- or</p> <p>12 how frequent is it that MSAs come to you with questions?</p> <p>13 Do you think they ask you questions daily?</p> <p>14 A. No.</p> <p>15 Q. And if an MSA does not have any questions on a</p> <p>16 particular day, what are you doing? What is your job on</p> <p>17 a day-to-day basis if not answering questions from MSAs?</p> <p>18 A. Performing MSA duties along with them.</p> <p>19 Q. And in those duties, are you doing the exact</p> <p>20 same job as other MSAs?</p> <p>21 A. Yes.</p> <p>22 Q. Please look at Exhibit 4, what is marked as</p> <p>23 Exhibit 4. Is this the CSL Plasma Medical Staff</p> <p>24 Reference - Conditions Guidelines?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 13</p> <p>1 trained in reception first.</p> <p>2 Q. Was that a medical reception technician?</p> <p>3 A. Yes.</p> <p>4 Q. And after you finished your medical reception</p> <p>5 technician training, did you work with the medical</p> <p>6 reception technician?</p> <p>7 A. Yes.</p> <p>8 Q. Do you know how long you worked as a medical</p> <p>9 reception technician?</p> <p>10 A. No. Shortly after I was transferred to the</p> <p>11 training for the medical staff.</p> <p>12 Q. How long did it take you to get trained on the</p> <p>13 conditions guidelines?</p> <p>14 A. I can't recall at this time.</p> <p>15 Q. Did you ever train anyone else on them?</p> <p>16 A. Yes.</p> <p>17 Q. Approximately how many staff would you say that</p> <p>18 you've trained on the conditions guidelines? Just an</p> <p>19 approximation.</p> <p>20 A. Approximately five, six.</p> <p>21 Q. Are the conditions guidelines supposed to be</p> <p>22 strictly followed?</p> <p>23 A. Yes. What our guidelines tells us to do, we</p> <p>24 have to abide by that.</p> <p>25 Q. Are there parts of the conditions guidelines</p>



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14 to 17

<p style="text-align: right;">Page 14</p> <p>1 that are open to interpretation?</p> <p>2 A. If we had any question, we would get</p> <p>3 clarification from our center physician.</p> <p>4 Q. So you are not supposed to make -- you are not</p> <p>5 supposed to interpret the guidelines, but rather go to</p> <p>6 the center physician?</p> <p>7 A. If we need clarification on anything, we would</p> <p>8 have to contact the center physician.</p> <p>9 Q. So what's an example of a time that you would</p> <p>10 need clarification on something?</p> <p>11 A. I can't recall at this time.</p> <p>12 Q. When was the last time that you needed</p> <p>13 clarification on something and had to go to the center</p> <p>14 physician?</p> <p>15 A. I believe it was for medications.</p> <p>16 Q. And was that a donor who was taking a</p> <p>17 medication?</p> <p>18 A. Donor was taking multiple medications.</p> <p>19 Q. And what prompted you to go to the center</p> <p>20 physician about the multiple medications?</p> <p>21 A. Due to the amount of medications, I questioned</p> <p>22 exactly what the donor was taking, what -- for what</p> <p>23 reason, and questioned the center physician if the donor</p> <p>24 was suitable to donate or not.</p> <p>25 Q. While you're using the conditions guidelines,</p>	<p style="text-align: right;">Page 16</p> <p>1 medical director or center physician?</p> <p>2 A. Anytime we need a clarification on any subject.</p> <p>3 Q. So was it based on when you didn't know the</p> <p>4 answer? And that varies, depending on who the MSA was;</p> <p>5 is that right?</p> <p>6 A. I don't understand.</p> <p>7 Q. If you don't know the answer to something, then</p> <p>8 you're supposed to call the center medical director; is</p> <p>9 that right?</p> <p>10 A. Yes.</p> <p>11 Q. And what about if another MSA didn't know the</p> <p>12 answer to something, was he or she supposed to call the</p> <p>13 center medical director?</p> <p>14 A. They can always contact Rey. And if they</p> <p>15 didn't know the answer, then, yes, they would contact the</p> <p>16 center physician.</p> <p>17 Q. Do you know if there's anything in the</p> <p>18 conditions guidelines about surgery?</p> <p>19 A. Excuse me?</p> <p>20 Q. Do you know if there's anything in the</p> <p>21 conditions guidelines about surgery?</p> <p>22 A. Depending on what type of surgery.</p> <p>23 Q. What does it say about surgery?</p> <p>24 A. There's major surgery and minor surgery.</p> <p>25 Q. What does it say about major surgery?</p>
<p style="text-align: right;">Page 15</p> <p>1 are you permitted to use your own clinical judgment on</p> <p>2 aspects of the guidelines?</p> <p>3 A. Yes.</p> <p>4 Q. How do you know when you're supposed to use</p> <p>5 your own clinical judgment versus when you're supposed to</p> <p>6 get the center physician involved?</p> <p>7 A. As far as with sign of -- symptoms of</p> <p>8 infection, something that we've been trained on and our</p> <p>9 center physician feels confident that we can determine,</p> <p>10 then, yes. But if we have any other question, we have to</p> <p>11 contact our center physician.</p> <p>12 Q. So if you've been trained on something, then</p> <p>13 you're allowed to use your own clinical judgment about</p> <p>14 it; is that right?</p> <p>15 A. Yes.</p> <p>16 Q. And were there written protocols about the</p> <p>17 types of cases that you're supposed to discuss with the</p> <p>18 center medical director or center physician?</p> <p>19 A. What do you mean?</p> <p>20 Q. Was there anything written about the times that</p> <p>21 you're supposed to call the center medical director or</p> <p>22 the times that you're supposed to call the center</p> <p>23 physician?</p> <p>24 A. No.</p> <p>25 Q. How did you know when to call the center</p>	<p style="text-align: right;">Page 17</p> <p>1 A. Acceptable if at least four months since</p> <p>2 procedure.</p> <p>3 Q. Does that mean it's talking about a past</p> <p>4 surgery, the past four months?</p> <p>5 A. Yes, so as long as it's been at least the</p> <p>6 four-month period.</p> <p>7 Q. Why is that, that it has to have been at least</p> <p>8 four months?</p> <p>9 A. Enough time for the donor to heal, for their</p> <p>10 safety, before they're able to donate.</p> <p>11 Q. How many times in a seven-day period are donors</p> <p>12 allowed to donate?</p> <p>13 A. Two times.</p> <p>14 Q. And why is there a restriction on the number of</p> <p>15 times a donor can donate in each week?</p> <p>16 A. Because we are taking their plasma, their</p> <p>17 fluid, and their body has to be able to replenish that.</p> <p>18 It's for their safety. There's those restrictions.</p> <p>19 Q. And how long does it take to replenish the</p> <p>20 plasma supply?</p> <p>21 A. I cannot recall the exact amount of time at</p> <p>22 this time.</p> <p>23 Q. Is there anything in the conditions guidelines</p> <p>24 about a donor's future surgery?</p> <p>25 A. No.</p>

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18 to 21

<p style="text-align: right;">Page 18</p> <p>1 Q. Are MSAs supposed to ask about future surgical 2 procedures? 3 A. If a donor does mention, then we can get more 4 information, but no. 5 Q. What kind of information would you then try to 6 get? 7 A. The reason for surgery. 8 Q. Do you also try to find out when the surgery is 9 scheduled? 10 A. Yes. 11 Q. If a donor says that they don't have any 12 surgery scheduled, would that impact donation that day? 13 A. We would have to contact our center physician. 14 Q. The protocol would be -- if a donor says, I may 15 need surgery. I don't have anything scheduled, your 16 protocol is that you would then need to contact the 17 center physician; is that right? 18 A. We would first evaluate the donor as to the 19 reason why they would need surgery. 20 Q. What types of reasons would permit donation 21 that day? What types of upcoming surgeries would permit 22 donations? 23 A. If a person was to have surgery, one reason -- 24 if someone had an active infection or if someone had an 25 injury, then at that time it wouldn't be ideal for them</p>	<p style="text-align: right;">Page 20</p> <p>1 the center physician; is that correct? 2 A. If we weren't sure as to -- as far as, you 3 know, what type of situation they were having, we would 4 contact our center physician, relay the -- what type of 5 issues are -- condition the donor was in and if he's okay 6 to donate. 7 Q. And then would you follow the input or advice 8 of the center physician? 9 A. Yes. 10 Q. What is marked as Exhibit 4 are the conditions 11 guidelines. I'm going to ask you to look at the top 12 right-hand corner. Do you see it says page blank of 71? 13 A. Yes. 14 Q. Turn to what is marked as page 3 of 71. 15 A. Okay. 16 Q. There is a box. And in the middle of the box, 17 it says "if." And then it has unsteady gait, falling, or 18 dizziness. Do you see that? 19 A. I see the unsteady gait, falling, dizziness, 20 yes. 21 Q. What is an unsteady gait? 22 A. Normal balanced walk. 23 Q. So -- I'm sorry. An unsteady gait is 24 somebody -- the way you answered the question was an 25 unsteady gait was someone with a normal balanced walk.</p>
<p style="text-align: right;">Page 19</p> <p>1 to donate, for their safety. 2 Q. And how would it impact their safety? 3 A. A person needs their plasma in order to heal. 4 And, also, if they do have an infection, they're actively 5 passing that infection along the plasma when they donate 6 it. 7 Q. And if a donor does not volunteer any 8 information about an upcoming surgery, that is not 9 something that MSAs routinely ask; is that correct? 10 A. Correct. 11 Q. And if a donor had said that they had a 12 long-term problem, such as a knee issue, and intended to 13 have a knee replacement, would they be allowed to donate? 14 A. We would contact the center physician. 15 Q. So is that something that you wouldn't be able 16 to answer on your own? 17 A. Just depending on the donor's situation, our 18 doctor would have to evaluate and determine if they're 19 suitable to continue donating. 20 Q. So typically -- or the correct protocol is to 21 then contact the center physician if a donor were to 22 disclose that; is that right? 23 A. That's something we would have to check with 24 our center physician. 25 Q. Right. So the protocol would be to check --</p>	<p style="text-align: right;">Page 21</p> <p>1 A. Oh, sorry. I didn't hear you correctly. The 2 phone was -- 3 Q. That -- no, that's fine. I just want to get 4 clarification. So what is an unsteady gait? 5 A. If someone is unbalanced, if someone is 6 limping, if someone is kind of like having a hard time 7 walking, sort of thing, where it's not balanced. 8 Q. And what is it about someone who is limping 9 that would prevent them from donating plasma? 10 A. If someone is limping, we have to find out the 11 reason why. Someone could be in pain. That person can 12 be injured. There would be a reason as to why they're 13 limping. 14 Q. And if the person says that they were in pain, 15 would they be restricted from donating that day? 16 A. At that time they're not well and healthy, so 17 yes. 18 Q. So anytime a donor says that they have a pain 19 in their body, they're restricted from donating; is that 20 correct? 21 A. We would have to evaluate the donor and find 22 out why they are in pain. 23 Q. Is it possible that somebody who says that they 24 are in pain would be allowed to donate, depending on what 25 you found out?</p>

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22 to 25

<p style="text-align: right;">Page 22</p> <p>1 A. We would have to get clarification from our 2 center physician. 3 Q. Someone who uses a cane, considered to have an 4 unsteady gait? 5 A. Excuse me? 6 Q. Someone who uses a cane, considered to have an 7 unsteady gait? 8 A. Not necessarily, no. 9 Q. When would somebody with a cane be considered 10 to have an okay gait? 11 A. If with the cane they do have steady gait. But 12 if -- even with the cane they have unsteady gait, that 13 wouldn't be acceptable. 14 Q. Okay. So somebody who uses a cane may or may 15 not have a steady gait; is that right? 16 A. Correct. 17 Q. And how do you know what is considered an 18 unsteady gait? 19 A. By watching the donor walk. 20 Q. Were you trained on how to watch the donor 21 walk? 22 A. Yes. 23 Q. And what did you learn about watching the donor 24 walk? How were you trained on it? 25 A. Anytime during a physical, before, we're</p>	<p style="text-align: right;">Page 24</p> <p>1 cane. 2 Q. But you would ask follow-up questions if you 3 saw that they used a cane? 4 A. Yes. 5 Q. So by itself using a cane is not enough to 6 exclude someone; is that correct? 7 A. Depending on the situation, why they would need 8 the cane, and also if we needed to call center physician. 9 Q. So MSAs are supposed to call the center 10 physician with any confusion or gray area on the 11 conditions guidelines; is that right? 12 A. Anytime, yes, we need clarification, we can 13 always call the center physician. 14 Q. On the same page, page 3 of 71, you see the 15 portion where it says transfer to donor bed? 16 A. Yes. 17 Q. What does it mean transfer to donor bed? 18 A. If the donor is able to get on and off the 19 donor bed without any assistance. 20 Q. And how do you determine whether or not the 21 donor can get on and off the donor bed? 22 A. We can actually take them to the donor floor, 23 to the donor bed, and we also have the medical table and 24 the medical offices. 25 Q. And do you ask the donor to do that?</p>
<p style="text-align: right;">Page 23</p> <p>1 supposed watch the gait. So that's what I was trained. 2 If anytime there is any abnormality when they're walking, 3 we need to investigate why. 4 Q. And is it fair to say that if you find out why 5 there's an abnormality in the gait, that it's not the 6 gait by itself that means they can't donate; it's the 7 reason behind the gait? Is that right? 8 A. Per our guidelines, if it says -- if -- it says 9 here unsteady gait, so it would be to defer. But, yes, 10 we can also see why they have an unsteady gait. 11 Q. Because there are times that someone may have 12 an unsteady gait that doesn't actually impact their 13 ability to donate; is that right? 14 A. We would have to get center physician 15 clarification on that. 16 Q. So the fact that someone limps is not just by 17 itself enough to exclude someone from donating; is that 18 right? 19 A. According to our guidelines with unsteady gait, 20 yes, it would be. But we can also get center physician 21 to determine what's going on with the donor. Why are 22 they limping? 23 Q. Is the fact that someone uses a cane by itself 24 enough to exclude someone from donating? 25 A. We would need to evaluate why they need the</p>	<p style="text-align: right;">Page 25</p> <p>1 A. During physicals they are required to get on 2 and off the medical table, so we assess at that point. 3 And we also assess on the donor floor while they get on 4 and off the donor bed. 5 Q. And if they can transfer to and from the donor 6 bed without assistance and they meet all other criteria, 7 am I right to say that they are allowed to donate? 8 A. According to our medical staff reference, yes. 9 Q. Are there any SOPs about deferring donors? 10 A. What do you mean? 11 Q. Do you have any written guidelines about when 12 to defer donors? 13 A. As far as our medical staff reference -- just 14 tells us when they are not acceptable. 15 Q. Are there -- are there additional SOPs about 16 deferring donors? 17 A. I can't recall at this time. 18 Q. Are there any SOPs about deferring donors who 19 have or may have surgery at some point in the future? 20 A. I'm not sure at this time. 21 Q. Are there SOPs about the conduct of donors? 22 A. What do you mean? 23 Q. Are there any SOPs about how to handle donor 24 conduct, what to do about donor conduct, what is 25 acceptable donor conduct?</p>

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26 to 29

<p style="text-align: right;">Page 26</p> <p>1 A. I don't recall at this time.</p> <p>2 Q. During your daily duties, what SOPs do you</p> <p>3 refer to?</p> <p>4 A. The medical staff reference.</p> <p>5 Q. Are there others that you refer to?</p> <p>6 A. There could be others. I don't remember the</p> <p>7 exact CTRs or SOPs, but yes.</p> <p>8 Q. At what -- it's okay if you don't remember the</p> <p>9 exact CTR number, but what would they refer to? What</p> <p>10 type of information would the SOP have that you would</p> <p>11 want to refer to?</p> <p>12 A. As far as information that wouldn't be in the</p> <p>13 medical staff reference, for -- how can I say? -- for</p> <p>14 reactive testing or if -- situations where the donor has</p> <p>15 traveled to other areas.</p> <p>16 Q. And that's not listed in the medical staff</p> <p>17 reference?</p> <p>18 A. Those are other SOPs.</p> <p>19 Q. Okay. And do you refer to those frequently?</p> <p>20 A. Just depending on the donors, you know, who</p> <p>21 that situation pertains to.</p> <p>22 Q. And are there other CSL policies or procedures</p> <p>23 that you refer to aside from what we've discussed and the</p> <p>24 conditions guidelines?</p> <p>25 A. I can't recall at this time.</p>	<p style="text-align: right;">Page 28</p> <p>1 Q. Do you know if a donor who uses a cane has ever</p> <p>2 been allowed to donate?</p> <p>3 A. I believe so, yes.</p> <p>4 Q. A donor with a limp ever been allowed to</p> <p>5 donate?</p> <p>6 A. I'm not sure. I don't remember.</p> <p>7 Q. Did any donor ever express to you any</p> <p>8 dissatisfaction with their experience at CSL Plasma?</p> <p>9 A. Yes.</p> <p>10 Q. What did they tell you about their</p> <p>11 dissatisfaction?</p> <p>12 A. They're not -- they're just not happy that they</p> <p>13 weren't able to donate or be able to get the money if</p> <p>14 they were to donate plasma.</p> <p>15 Q. What were you supposed to do if that happened?</p> <p>16 A. What do you mean?</p> <p>17 Q. What were you supposed to do if a donor</p> <p>18 complained to you and said that they were dissatisfied?</p> <p>19 A. Try my best to explain as to the reason why</p> <p>20 they weren't able to donate.</p> <p>21 Q. Were you supposed to get any supervisor</p> <p>22 involved?</p> <p>23 A. If the donor started being loud or volatile</p> <p>24 where I felt my safety was in question, yes.</p> <p>25 Q. What about if the donor asked to speak to a</p>
<p style="text-align: right;">Page 27</p> <p>1 Q. You mentioned earlier the phrase CTR. What</p> <p>2 does CTR mean?</p> <p>3 A. I can't recall at this time.</p> <p>4 Q. Do you know what it might stand for?</p> <p>5 A. I don't remember right now.</p> <p>6 Q. -- you use that -- those letters, though, do</p> <p>7 you use them to describe things in your job or at CSL</p> <p>8 Plasma?</p> <p>9 A. They're a certain SOP, standard of operations.</p> <p>10 Q. But CTR, is that -- do you refer to things as</p> <p>11 CTR number something? Is that a typical way for you to</p> <p>12 refer to things?</p> <p>13 A. Yes.</p> <p>14 Q. Did you ever talk to the center physician about</p> <p>15 a donor with an unsteady gait?</p> <p>16 A. Not that I can recall.</p> <p>17 Q. Did you ever talk to the center physician about</p> <p>18 a donor who used a cane?</p> <p>19 A. Yes, I believe so. Yes.</p> <p>20 Q. Do you know what came out of that question or</p> <p>21 that discussion?</p> <p>22 A. I -- I do not remember.</p> <p>23 Q. Was the donor allowed to donate, who used a</p> <p>24 cane?</p> <p>25 A. I do not remember.</p>	<p style="text-align: right;">Page 29</p> <p>1 supervisor?</p> <p>2 A. Of course.</p> <p>3 Q. Have you had to get supervisors involved in the</p> <p>4 past?</p> <p>5 A. Yes.</p> <p>6 Q. Have you ever had a plasma donor get angry with</p> <p>7 you?</p> <p>8 A. Yes.</p> <p>9 Q. What did they do that made you know they were</p> <p>10 angry?</p> <p>11 A. They started yelling and stood up and walked</p> <p>12 towards me.</p> <p>13 Q. And what did you do?</p> <p>14 A. Call my center manager as soon as I can and try</p> <p>15 to get to safety.</p> <p>16 Q. And so what happened with that donor?</p> <p>17 A. What do you mean?</p> <p>18 Q. Well, did the supervisor come over and talk to</p> <p>19 the donor? What happened?</p> <p>20 A. Yes. I believe they went into the office and</p> <p>21 sat down and talked with the donor.</p> <p>22 Q. So was that donor allowed to donate later?</p> <p>23 A. I don't recall.</p> <p>24 Q. Was that donor deferred?</p> <p>25 A. They're already deferred to begin with, I</p>

Melanie Garcia  
June 26, 2017

30 to 33

<p style="text-align: right;">Page 30</p> <p>1 believe was that situation.</p> <p>2 Q. So was the deferral based on something else, or</p> <p>3 was the deferral based on their behavior?</p> <p>4 A. I think in that particular situation, that</p> <p>5 deferral was for -- not for the behavior, but there has</p> <p>6 been times in the past where people are deferred for</p> <p>7 their behavior.</p> <p>8 Q. And what happens that would get somebody</p> <p>9 deferred for behavior?</p> <p>10 A. With that situation, there's been times</p> <p>11 where -- for other medical staff associates, where</p> <p>12 someone flung a door open and almost hit an MSA. Another</p> <p>13 person cornered an MSA and started slapping on the desk</p> <p>14 and almost hitting the MSA.</p> <p>15 Another few donors tend to threaten us,</p> <p>16 said they'll meet us outside and follow us, etc.</p> <p>17 Q. In those situations where -- that sounds like</p> <p>18 they were a physical threat. Is that right, or physical</p> <p>19 actions?</p> <p>20 A. Well, not with the threatening, just the other</p> <p>21 situations, yes, where they stood up and got loud or</p> <p>22 cussing.</p> <p>23 Q. Would you be the one to tell potential donors</p> <p>24 that they were deferred?</p> <p>25 A. For what reason?</p>	<p style="text-align: right;">Page 32</p> <p>1 of a deferral?</p> <p>2 A. No.</p> <p>3 Q. Was a person who was deferred -- ever talked to</p> <p>4 the center manager -- has a person who was deferred ever</p> <p>5 talked to the center manager and then subsequently be</p> <p>6 allowed to donate?</p> <p>7 A. Not that I can recall, no.</p> <p>8 Q. What if the person can prove that the reason</p> <p>9 for a deferral was wrong?</p> <p>10 A. What do you mean?</p> <p>11 Q. What if there's something that can be proven to</p> <p>12 be incorrect about the reason for deferral?</p> <p>13 A. Then, they would be okay to donate.</p> <p>14 Q. And are you authorized to defer someone for</p> <p>15 donating for any other reason than those listed here on</p> <p>16 the conditions guidelines?</p> <p>17 A. What do you mean?</p> <p>18 Q. Can you refer someone -- I'm sorry. Can you</p> <p>19 defer someone for reasons that are not listed here on the</p> <p>20 conditions guidelines?</p> <p>21 A. I'm not sure I understand what you're asking.</p> <p>22 Q. Are there times that you defer people for</p> <p>23 reasons that are not listed in the conditions guidelines?</p> <p>24 So you're saying -- you're telling someone that they're</p> <p>25 deferred, but the reason for deferral isn't actually</p>
<p style="text-align: right;">Page 31</p> <p>1 Q. For medical reason.</p> <p>2 A. Yes.</p> <p>3 Q. And would you tell them why they were being</p> <p>4 deferred?</p> <p>5 A. Yes.</p> <p>6 Q. What happens after someone gets deferred?</p> <p>7 A. We notify them the reason why. Once we know</p> <p>8 the donor understands, the donor would leave the center.</p> <p>9 Q. So it is the MSA's job to explain to the person</p> <p>10 why they're being deferred; is that right?</p> <p>11 A. Yes.</p> <p>12 Q. The -- or -- I'm sorry. Can the person being</p> <p>13 deferred disagree with the reason for deferral?</p> <p>14 A. Yes.</p> <p>15 Q. And what would happen if someone said they</p> <p>16 disagreed with the reason for deferral?</p> <p>17 A. Find out why they disagree.</p> <p>18 Q. And what were you supposed to do with that</p> <p>19 information?</p> <p>20 A. With whatever certain situation for the</p> <p>21 deferral -- if at that time they're deferred, they're</p> <p>22 deferred. We can try to explain best we can, or we can</p> <p>23 get a center manager or -- or supervisor, which would be</p> <p>24 key, or get a center manager.</p> <p>25 Q. Could the potential donor appeal the decision</p>	<p style="text-align: right;">Page 33</p> <p>1 written down here in the conditions guidelines?</p> <p>2 A. Not that I can recall.</p> <p>3 Q. So your deferrals really need to be listed in</p> <p>4 the conditions guidelines; is that right? In other</p> <p>5 words, if you are going to defer someone, the reason</p> <p>6 provided has to be written down somewhere in these</p> <p>7 conditions guidelines; is that right?</p> <p>8 A. Well, the conditions guideline is a guideline,</p> <p>9 yes. If we have any other questions that we would feel</p> <p>10 the donor's safety is at risk or the plasma would be --</p> <p>11 the quality would be affected in any way, we can always</p> <p>12 call center physician.</p> <p>13 Q. Okay. So there are reasons you could defer</p> <p>14 someone that are not listed in these conditions</p> <p>15 guidelines; is that right?</p> <p>16 A. We would have to talk to our center physician.</p> <p>17 But like I said, it's a guideline mainly. Our main</p> <p>18 concern is the safety of the donor.</p> <p>19 Q. Okay. Could donors tell the MSA to call a</p> <p>20 center physician? Could they request that the center</p> <p>21 physician be called about an issue?</p> <p>22 A. Yes, could.</p> <p>23 Q. And have you ever done that? Has a donor ever</p> <p>24 asked you to call the center physician and you did?</p> <p>25 A. Believe, yes. Was over medications.</p>





Michelle Mailey  
April 11, 2017

14 to 17

Page 14	Page 15
<p>1 A. Yes.</p> <p>2 Q. And why did you leave Nueces County Jail?</p> <p>3 A. Because I got a better opportunity.</p> <p>4 Q. Were you terminated from CSL Plasma?</p> <p>5 A. No, I was not.</p> <p>6 Q. And were you terminated from Nueces County</p> <p>7 Jail?</p> <p>8 A. No, I was not.</p> <p>9 Q. And what was your job title while you were</p> <p>10 working at CSL Plasma?</p> <p>11 A. MSA.</p> <p>12 Q. What does MSA stand for?</p> <p>13 A. Medical staff associate.</p> <p>14 Q. What were your job duties as an MSA?</p> <p>15 A. Donor screening. We took care of donor</p> <p>16 reactions. We did the donor -- donor qualification</p> <p>17 physicals.</p> <p>18 Q. Donor qualification physicals?</p> <p>19 A. Yes. They have a physical before you can</p> <p>20 donate.</p> <p>21 Q. Okay. I'm going to ask you about --</p> <p>22 A. Physical assessment.</p> <p>23 Q. Okay. I'm going to ask you about each of those</p> <p>24 things. What -- you said one of your job duties was a</p> <p>25 donor screening. What does that mean? What is a donor</p>	<p>1 screening?</p> <p>2 A. Donor screening, they're brought into a booth.</p> <p>3 We review the questionnaire. They get their finger stuck</p> <p>4 to check the protein. I don't remember everything that</p> <p>5 goes on, vital signs, weight.</p> <p>6 MSAs did new donor screening, which</p> <p>7 involved documenting tattoos, medical conditions,</p> <p>8 medications, medical histories. That's on a new donor.</p> <p>9 Q. On a new donor.</p> <p>10 A. New donor screenings were more in -- more</p> <p>11 in-depth.</p> <p>12 Q. So just to clarify, for previous donors,</p> <p>13 weight, vital signs, finger sticks. And you brought them</p> <p>14 into the booth to do those things?</p> <p>15 A. If I was screening, yes. I mean, we -- if we</p> <p>16 were called by another staff member to assess another</p> <p>17 situation, then we assessed another situation. During</p> <p>18 the screening process, if something comes up medical,</p> <p>19 then they would call the MSA.</p> <p>20 Q. So typically did you do the donor screening,</p> <p>21 then?</p> <p>22 A. I did several. I did probably hundreds of</p> <p>23 donor screenings.</p> <p>24 Q. And was that part of your normal job duties?</p> <p>25 A. Yes.</p>
Page 16	Page 17
<p>1 Q. And you said that you would be called in to do</p> <p>2 an assessment occasionally?</p> <p>3 A. Well, if something came up during a donor</p> <p>4 screening process or if there was a problem, they would</p> <p>5 call the MSAs, because we were the medical.</p> <p>6 Q. Typically would someone else be doing the donor</p> <p>7 screening?</p> <p>8 A. Yes, one of the screeners --</p> <p>9 Q. Okay.</p> <p>10 A. -- front. I don't remember what their title</p> <p>11 was.</p> <p>12 Q. And you were called into the donor screening if</p> <p>13 there was something unusual?</p> <p>14 A. Or I was screening that day.</p> <p>15 Q. Or you were screening.</p> <p>16 A. If there was a big line, the MSAs assisted in</p> <p>17 the front screening donors.</p> <p>18 Q. And you also said that you -- one of your job</p> <p>19 duties was donor reactions?</p> <p>20 A. Uh-huh.</p> <p>21 Q. What does donor reactions mean?</p> <p>22 A. They have a negative reaction to the donation</p> <p>23 process.</p> <p>24 Q. And what is a negative reaction to the donation</p> <p>25 process?</p>	<p>1 A. There's a lot of different things that can</p> <p>2 happen. Some of them vomit. Some of them faint.</p> <p>3 There's a lot of different things that happen. I can't</p> <p>4 remember them all. It's been a while. If we were called</p> <p>5 to the donor floor because there was something going on,</p> <p>6 we went and took care of it.</p> <p>7 Q. And what would you do if there was a donor</p> <p>8 reaction?</p> <p>9 A. Would depend on their reaction.</p> <p>10 Q. Would you provide medical care?</p> <p>11 A. Donor reactions generally consisted of an ice</p> <p>12 pack, getting them fluids. And if need be, they'd get an</p> <p>13 IV started. And if it was a severe reaction, EMS was</p> <p>14 activated.</p> <p>15 Q. And would you document this?</p> <p>16 A. Yes, in -- a donor reaction, yes.</p> <p>17 Q. Where would you document it?</p> <p>18 A. In the computer.</p> <p>19 Q. You also said that one of your job duties was</p> <p>20 donor qualifications?</p> <p>21 A. Yeah. It's part of the new donor process.</p> <p>22 Q. And what did that entail? What was the donor</p> <p>23 qualification --</p> <p>24 A. There's different things that can disqualify a</p> <p>25 donor. There's different things that need more</p>

Michelle Mailey  
April 11, 2017

18 to 21

<p style="text-align: right;">Page 18</p> <p>1 information. It just -- it -- it's case-specific. It's 2 each person specific, so it's hard to tell you what -- 3 there's a lot of different things that would cause an MSA 4 to have to be involved in coming and ask for more 5 information. 6 Q. And typically you would not be the person that 7 would come in to determine donor qualifications? 8 A. Something came up on the answer -- on the 9 donor's questionnaire. Yes, the MSA would have to get 10 more information. If one of the other staff members 11 asked for an MSA to come in because there was more 12 information needed, then the MSA would come in. 13 Q. And when you would go in as an MSA, what would 14 you do when you got into the room? 15 A. Would depend on the situation. 16 Q. Would you ask questions? 17 A. Yes. 18 Q. Would you ask questions to the donor? 19 A. Yes. 20 Q. What is an example of a question that you would 21 ask the donor? 22 A. Oh, my God. I don't know. Again, it's 23 case-specific. So if I don't have a case in front of me, 24 it's kind of hard to tell you what I'm going to ask. I 25 mean, I can't go back and remember every case that I ever</p>	<p style="text-align: right;">Page 19</p> <p>1 was involved in at CSL Plasma. It's case-specific, so I 2 don't know how to answer that. 3 Q. I'm not asking you about a specific instance. 4 I'm asking you to recall an example of the type of 5 question that you would ask once you were called -- 6 A. Okay. If a patient answered yes, they were on 7 medications, then we're going to interview them and find 8 out what medications, how long they've been on it, who 9 ordered it, why they're on it. 10 Q. And if they answer that they were on 11 medication, was that not something that the individual 12 that was already screened, then, would be able to assess? 13 Is that why you were called in? 14 A. Well, the question would have been answered by 15 the donor on the donor screening process in the front 16 where they answer the little questions. If something 17 comes in when then they come -- then, they come in the 18 booth for screening. 19 If something is not -- or out of the norm 20 on the donor screening -- the little computer screen 21 questionnaire, then they're going to call an MSA. They 22 get an MSA tag, and the MSA has to finish the process. 23 Q. So would an MSA be involved any time that the 24 questionnaire had something out of the ordinary? 25 A. If the screener felt that an MSA was necessary,</p>
<p style="text-align: right;">Page 20</p> <p>1 they would give the donor an MSA tag and call an MSA, 2 like -- again, it was a case-specific thing. So it's 3 hard to say that every time they answer -- sometimes it 4 was just they misread the question. We still have to 5 ask. 6 Q. And would the screener make that determination 7 about whether to call -- 8 A. The screener -- 9 Q. -- MSA -- 10 A. -- sends the donor to the MSA. 11 Q. And who was your supervisor at CSL Plasma? 12 A. I had a lot of supervisors. 13 Q. Who was one of your supervisors? 14 A. At the time it was Dennis Thomas, Rey Vargas, 15 Nola Baker. 16 Q. Any other supervisors? 17 A. We had the -- the main manager. I don't 18 remember his name at the time. I didn't interact with 19 him as much. The managers were our direct supervisors. 20 Rey Vargas was the medical management. Dennis Thomas, 21 Nola Baker were center managers. 22 Q. So you've given the names Dennis Thomas, Rey 23 Vargas, Nola Baker. Did you have any other supervisors? 24 A. Yes. I said there was a main manager, but I do 25 not remember his name. I can't remember his name.</p>	<p style="text-align: right;">Page 21</p> <p>1 Q. Okay. I'll repeat. The main manager, whose 2 name you don't remember; Nola Baker; Rey Vargas; and 3 Dennis Thomas. Were there any other supervisors in 4 addition to those four individuals? 5 A. Not that I can recall. 6 Q. And where did you work before you were at CSL 7 Plasma? 8 A. Girling Home Health. 9 Q. How long have you been a nurse? 10 A. It will be 23 years this year. 11 Q. And did you do anything before you went into 12 nursing? 13 A. No. I went from high school to nursing school. 14 Q. Since you've left CSL Plasma, have you been 15 paid by them for anything? 16 A. No. I don't even donate there anymore. 17 Q. Did you list CSL Plasma as a job reference? 18 A. Yeah. It's in my job history. I listed it. 19 Q. And while you were there, were you ever 20 counseled or disciplined? 21 A. I don't remember. Not that I -- a write-up, 22 no. 23 Q. Did -- you did not receive any write-ups? 24 A. I don't recall being -- ever being written up, 25 no.</p>



Michelle Mailey  
April 11, 2017

30 to 33

<p style="text-align: right;">Page 30</p> <p>1 A. Yes. And anything that may have occurred on 2 the last donation. I mean, there's a lot of different 3 variables that questions would arise between donations. 4 It just depends on what happened the last donation. 5 I mean, an instance -- a reaction. You 6 know, if they had a reaction on their last visit, they're 7 not just going to come in and donate. The MSA usually 8 sees the patient first. 9 Q. So you mentioned a reaction as something that 10 could possibly make the MSA see the -- the donor first. 11 A. Uh-huh. 12 Q. What were other things that could possibly make 13 an MSA see the donor first? 14 A. Big gaps in time they were there, if anybody in 15 the front called an MSA. 16 Q. And were the front staff -- were they free to 17 uses their own judgment about whether to call an MSA or 18 not? 19 A. Yes. 20 Q. Were there protocols written down about when 21 they should call an MSA? 22 A. There's a lot of different protocols. I don't 23 recall all of them. 24 Q. But were there protocols about when to call 25 an -- an MSA?</p>	<p style="text-align: right;">Page 31</p> <p>1 A. I'm sure there were. 2 Q. Do you remember the names of those protocols? 3 A. I don't. 4 Q. I'm going to ask you about something that we 5 have labeled previously as Exhibit 4. And the exhibits 6 are here. I will show you what Exhibit 4 is. Have you 7 ever seen this before? 8 A. Yeah, years ago when I worked there. 9 Q. What is it? 10 A. Well, to answer that completely, I'd have to 11 read the entire thing. I know it's -- it's not the 12 entire book. This is medical stuff that triggers on what 13 we need to do medically. But I can tell you there's a 14 lot more to it than that. 15 Q. Okay. So I understand you're saying that 16 there's stuff missing from here. 17 A. Yes. 18 Q. Is that right? Okay. Do you notice what is 19 missing? 20 A. No. I just remember it being a lot more. 21 Q. In your recollection of the medical staff 22 reference, what did it contain? 23 A. Different instructions for if someone has this, 24 this is what it is. And if they have this, this is what 25 you do. Was a guideline.</p>
<p style="text-align: right;">Page 32</p> <p>1 Q. Are there any parts of this that are open to 2 interpretation? 3 A. Well, again, I don't know without reading the 4 entire thing. I mean, I don't know. 5 Q. So you do not know whether or not this was open 6 to interpretation; is that correct? 7 A. Without reading the entire thing, no, I do not 8 know. 9 Q. When you were at CSL Plasma, do you recall 10 whether or not you would interpret these guidelines? 11 A. No. We went by the guidelines. If there was a 12 question, we would go to somebody like Rey, or we would 13 call our medical director. 14 Q. I'm going to come back to that, because I am 15 wanting to ask questions about when you would go to Rey 16 or when you would go to the medical director. But I want 17 to ask a little bit more about the guidelines first. 18 Did you -- you did use these guide -- 19 guidelines when you were at CSL Plasma; is that right? 20 A. Yes. 21 Q. And how often did you refer to them? 22 A. Pretty much every time a new donor processed. 23 Q. So is it fair to say that with almost every new 24 donor, you would need to look at these for -- 25 A. Almost every new donor. It would depend on</p>	<p style="text-align: right;">Page 33</p> <p>1 what was on their questionnaire. 2 Q. Do you know who wrote these guidelines? 3 A. Exactly, no. It's -- they're corporate. 4 Q. So you believe CSL corporate wrote the 5 guidelines? 6 A. Well, I don't think CSL corporate wrote the 7 guidelines. But someone that works for CSL wrote the 8 guidelines, yeah. I'm pretty sure that the medical was 9 written by medical staff. 10 Q. And who trained you on these guidelines? 11 A. Melanie and Rey. They don't train you on every 12 single guideline. You're trained as an MSA. You're 13 taught how to use the guideline, how to use it as a 14 reference. 15 I mean, they don't sit there and go 16 through every -- it's -- training at CSL is, read this. 17 And then you take a test or you get asked questions. 18 Q. And you'd previously said that you took a lot 19 of these tests at CSL Plasma -- 20 A. Yes. 21 Q. -- is that right? And do they have a test -- 22 after every kind of training that you did, you'd have a 23 test to review? 24 A. To move on to the next portion. I don't -- 25 Q. Okay.</p>

Michelle Mailey

April 11, 2017

34 to 37

<p style="text-align: right;">Page 34</p> <p>1 A. -- remember how many parts there are to the MSA</p> <p>2 training, but there's more than one part. You had to</p> <p>3 test to go to the next part.</p> <p>4 Q. You said you received training on how to</p> <p>5 interpret these guidelines. What information were you</p> <p>6 given about how to interpret them?</p> <p>7 A. Well, I don't think I used the word interpret.</p> <p>8 We used the guidelines. We read the guidelines and</p> <p>9 followed the guidelines. When there was a question, we</p> <p>10 could call either the physician or we could go to Rey.</p> <p>11 Q. Well, I can ask you now since I was going to</p> <p>12 come back to these times that you had to ask questions to</p> <p>13 either Rey or the physician. Were you in charge or was</p> <p>14 it your job to use your judgment about whether or not to</p> <p>15 call Rey or the physician?</p> <p>16 A. Yes.</p> <p>17 Q. And how would you make the determination to</p> <p>18 call Rey or the --</p> <p>19 A. Depend on the --</p> <p>20 Q. -- physician?</p> <p>21 A. -- what was going on and what -- what the</p> <p>22 question was. Would just depend. Again, case-by-case</p> <p>23 basis.</p> <p>24 Q. So you are saying that these cases were</p> <p>25 supposed to be -- or these determinations were supposed</p>	<p style="text-align: right;">Page 35</p> <p>1 to be made on a case-by-case basis?</p> <p>2 A. Each person is different. Every person has</p> <p>3 different things. Every person got screened. Every</p> <p>4 person got questioned, and different things come up. And</p> <p>5 if you're not sure about what this says, you can call a</p> <p>6 physician or go to Rey for clarification.</p> <p>7 Q. You would call Rey or the physician when you</p> <p>8 are unsure?</p> <p>9 A. When you needed clarification.</p> <p>10 Q. And did you seek clarification because the</p> <p>11 guidelines were not --</p> <p>12 A. Either they weren't --</p> <p>13 Q. -- clear?</p> <p>14 A. -- clear or the -- the -- the case-specific</p> <p>15 issue was not necessarily on -- in the guideline.</p> <p>16 Q. And are you permitted to use your own clinical</p> <p>17 judgment to follow these guidelines?</p> <p>18 A. The MSAs are trusted to use their clinical</p> <p>19 judgment. That's why we're MSAs.</p> <p>20 Q. Do you know who the center medical director,</p> <p>21 the center physician, was while you were there?</p> <p>22 A. I don't remember his name. I think we had two</p> <p>23 while I was there. I don't remember either one of their</p> <p>24 name.</p> <p>25 Q. Would you call them? Did you ever speak with</p>
<p style="text-align: right;">Page 36</p> <p>1 them on the phone?</p> <p>2 A. Oh, yeah.</p> <p>3 Q. And you had previously said sometimes you would</p> <p>4 ask Rey, and sometimes you would ask the center</p> <p>5 physician. Under what circumstances would you ask Rey?</p> <p>6 A. If something was unclear on the medical</p> <p>7 reference or if I had a question about something, I would</p> <p>8 ask Rey or the medical director.</p> <p>9 Q. Was Rey always the first person that you would</p> <p>10 ask?</p> <p>11 A. If he was there. Otherwise, sometimes I might</p> <p>12 ask Melanie if I needed clarification on something. She</p> <p>13 had been there longer.</p> <p>14 Q. And how would you decide whether to ask Rey or</p> <p>15 to ask the center physician?</p> <p>16 A. Most of the time Rey was able to answer</p> <p>17 questions. If it was more in-depth or Rey would instruct</p> <p>18 me to call the medical director, I would call the medical</p> <p>19 director.</p> <p>20 Q. Did you ever call the medical director on your</p> <p>21 own first --</p> <p>22 A. Oh, yes.</p> <p>23 Q. -- without consulting Rey?</p> <p>24 A. Yes. If it was something that triggered me to</p> <p>25 call the medical director, I'd trigger the -- I'd call</p>	<p style="text-align: right;">Page 37</p> <p>1 the medical director.</p> <p>2 Q. And what's an example of a time that you called</p> <p>3 the medical director?</p> <p>4 A. I know I had to call him for medication</p> <p>5 clarification --</p> <p>6 Q. Okay.</p> <p>7 A. -- because it wasn't on the list. I mean, I</p> <p>8 can't recall every time I called him. I know I called</p> <p>9 him on several occasions for several different reasons on</p> <p>10 several different dates. I can't tell you when or why.</p> <p>11 Q. So you talked about the medical -- or -- I'm</p> <p>12 sorry. The medication clarification was one time that</p> <p>13 you called the medical director directly. Can you recall</p> <p>14 other instances?</p> <p>15 A. Oh, yeah, donor reactions. There's a lot of</p> <p>16 different reasons we would have called. I can't sit here</p> <p>17 and tell you every time I called the medical director.</p> <p>18 Can't sit here and tell you every time I went and talked</p> <p>19 to Rey. I can't tell you every time I went and asked</p> <p>20 Melanie a question.</p> <p>21 Q. Right. And I'm not --</p> <p>22 A. I worked there a long time.</p> <p>23 Q. I'm not asking you to recall every single time,</p> <p>24 because I understand that you may not be able to do that.</p> <p>25 But I am asking about examples of times that you had --</p>

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<p style="text-align: right;">Page 38</p> <p>1 had to call the medical director directly. 2 I do understand that you may not recall 3 every time. You've talked about the medication 4 clarification, the donor reaction. What other instances 5 might you call the medical director direct -- 6 A. I don't know. I mean, I honestly don't know. 7 There's a lot of different reasons we would call a 8 medical director or Rey. I can't give you every single 9 example of why I called the medical director or I asked 10 Rey a question. I don't know. 11 Q. And so you cannot recall any other time that 12 you would have asked Rey a question -- 13 A. Can I sit here and tell you why exactly I went 14 and asked Rey a question? No, I cannot. I don't 15 remember. It was a while back. We see a lot of donors. 16 I don't remember. 17 Q. Were there any protocols in place about the 18 times that you were supposed to call the center medical 19 director, center physician? 20 A. Oh, yes. 21 Q. And what protocols were those? 22 A. I don't remember. 23 Q. Do you think they were written protocols? 24 A. I'm sure they were. I just -- I don't 25 remember. I know there were certain times that we had to</p>	<p style="text-align: right;">Page 39</p> <p>1 call the doctor. I just don't remember what they were. 2 Q. So there were times that were indicated as you 3 must call the doctor; is -- 4 A. Yes. 5 Q. -- that correct? 6 A. Certain severity of reactions, we had to notify 7 the doctor. I mean, I don't remember what the policies 8 and procedures were. I -- I don't work there. I don't 9 remember. 10 Q. I'm going to ask you to turn to page 3 of this 11 exhibit. And there -- there's front and back, so 12 apologies for that confusion, but page 3. You can take 13 off the paper clip. 14 So let's make sure we're looking at the 15 same page. I don't think we are. Page 3 at the top. 16 Yes. Okay. And on this page, it says: Disabilities. 17 See SOP for specific guidance. 18 Was there a specific SOP about 19 disabilities? 20 A. Yeah, it's right there. 21 Q. So when it says see SOP for specific guidance, 22 you're saying that this is referring to this page? 23 A. This is the -- if I -- I don't -- I don't 24 remember what a SOP is. This was our medical staff 25 reference. This is what we went by.</p>
<p style="text-align: right;">Page 40</p> <p>1 Q. So it is your testimony that there was nothing 2 else that you referred to having to do with disabilities; 3 is that correct? 4 A. It says see SOP for specific guidelines. I 5 don't recall. I'm sure I went to the SOP. I don't 6 remember even what it is today. 7 Q. SOP may stand for standard operating procedure. 8 A. Uh-huh. 9 Q. And it may be a written document. 10 A. Uh-huh. 11 Q. See SOP for specific guidance. You're saying 12 that you cannot remember if there is any other written 13 documentation about disabilities; is that correct? 14 A. It says there's an SOP for it, so I'm sure 15 there is. Can I recall if I've actually -- no, I don't 16 recall what it says or what's on it. No. 17 Q. I'd like to review this specific page -- 18 A. Uh-huh. 19 Q. -- and some of the pieces of the chart on this 20 page. There is a "if" column. 21 A. Uh-huh. 22 Q. And then that is a "then" column. 23 A. Uh-huh. 24 Q. The "if," does that mean if the donor presents 25 with these things?</p>	<p style="text-align: right;">Page 41</p> <p>1 A. Uh-huh. 2 Q. And the "then" column, does that mean that CSL 3 Plasma may find them acceptable or for a deferral if 4 these things are present? 5 A. Uh-huh. Or if the donor screener came up with 6 this, this would trigger them to call an MSA. If they 7 found one of these ifs, then the MSA would come and do 8 more in-depth assessment. 9 Q. Okay. For the mental or behavioral on this 10 chart, it says if mental or behavioral; is that correct? 11 A. Yes. 12 Q. Then acceptable if able to give informed 13 consent, does not violate center standards; is that 14 correct? 15 A. Yes. 16 Q. What are the center standards that are 17 referenced here? 18 A. I don't recall. I know that behavior was a big 19 part of it. 20 Q. What kind of behavior was part of the center 21 standards? 22 A. Fighting, cursing at staff, threatening staff, 23 slamming doors, throwing things, fighting with another 24 donor, touching another donor, sexually harassing another 25 donor. There were a lot of reasons when it came to</p>

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<p style="text-align: right;">Page 42</p> <p>1 behavior.</p> <p>2 Q. And do you believe there were written policies</p> <p>3 on these?</p> <p>4 A. Oh, yes. And then the managers, of course,</p> <p>5 they do -- you know, it becomes a management issue.</p> <p>6 Q. And what happens when it becomes a management</p> <p>7 issue?</p> <p>8 A. It's a management issue. Manager takes over.</p> <p>9 Q. And the management handles whatever complaint</p> <p>10 has been made to them?</p> <p>11 A. Uh-huh.</p> <p>12 Q. Further on this chart, you see if unsteady</p> <p>13 gait, falling, or dizziness, then defer; is that right?</p> <p>14 A. Uh-huh.</p> <p>15 Q. I'm going to -- I just -- yes or no?</p> <p>16 A. Yes.</p> <p>17 Q. Thank you. For unsteady gait, falling, or</p> <p>18 dizziness -- I think I know what falling means. But can</p> <p>19 you please explain to me what would qualify as falling?</p> <p>20 A. Somebody falls down.</p> <p>21 Q. And for dizziness, is that self-reported</p> <p>22 dizziness?</p> <p>23 A. I would assume it would be self-reported</p> <p>24 dizziness. But you can kind of tell when somebody is,</p> <p>25 you know, swimming in their head, if they can't walk a</p>	<p style="text-align: right;">Page 43</p> <p>1 straight line.</p> <p>2 Q. Okay. So what does that look like? If it's</p> <p>3 not self-reported and you're observing it, what does</p> <p>4 dizziness look like?</p> <p>5 A. If someone is kind of doing this, it's a very</p> <p>6 good indication that they're not seeing right.</p> <p>7 Q. And I'm going to ask you -- I apologize.</p> <p>8 A. I don't know how to explain it in words.</p> <p>9 Q. Okay. I'm going to finish my question. You</p> <p>10 said doing this, which unfortunately the court reporter</p> <p>11 can't take down. So if you could --</p> <p>12 A. Swerving back and forth. I don't know if</p> <p>13 walking is swerving. Stumbling can be an indication of</p> <p>14 dizziness. There's a lot of different indications that</p> <p>15 someone could be dizzy or light-headed.</p> <p>16 I mean, someone can stand up, get dizzy</p> <p>17 and -- and fall down. It's -- there's a lot of</p> <p>18 indications for dizziness.</p> <p>19 Q. And what is unsteady gait on this?</p> <p>20 A. Unsteady gait would be an unsteady gait.</p> <p>21 They're not steady on their feet.</p> <p>22 Q. So would falling be an unsteady gait?</p> <p>23 A. Falling usually results from an unsteady gait.</p> <p>24 Falling is an action, not a symptom.</p> <p>25 Q. And is walking slowly considered an unsteady</p>
<p style="text-align: right;">Page 44</p> <p>1 gait?</p> <p>2 A. No. That's walking slowly.</p> <p>3 Q. Would limping be considered an unsteady gait?</p> <p>4 A. Yes. That's not a normal gait, so it would be</p> <p>5 an unsteady gait.</p> <p>6 Q. So is anything that's not a normal gait an</p> <p>7 unsteady gait?</p> <p>8 A. If it causes issues with ambulation, it is an</p> <p>9 unsteady gait.</p> <p>10 Q. And if it does not cause issues with</p> <p>11 ambulation, is it not an unsteady gait?</p> <p>12 A. That would depend -- I mean, it would depend on</p> <p>13 the severity. You can have -- I mean, anyone who cannot</p> <p>14 walk on their two feet, it's an unsteady gait. If they</p> <p>15 are using crutches, cane, walker, they're unsteady. They</p> <p>16 require a stabilizing device.</p> <p>17 Q. You said anybody that cannot walk on their own</p> <p>18 two feet has an unsteady gait; is that correct?</p> <p>19 A. Well, unless they're in a wheelchair, then they</p> <p>20 don't walk at all, but --</p> <p>21 Q. So if somebody can walk on their own two feet,</p> <p>22 do they have a steady gait?</p> <p>23 A. Without assistive device, it's -- it's probable</p> <p>24 that they have a steady gait. It's not a hundred percent</p> <p>25 that their gait is steady. I mean, you can be unsteady</p>	<p style="text-align: right;">Page 45</p> <p>1 on your feet.</p> <p>2 Q. So if you can --</p> <p>3 A. A dizzy person can become unsteady.</p> <p>4 Q. If you can walk on your own two feet without an</p> <p>5 assistive device, you've said it's probable that they</p> <p>6 have a steady gait. When would they not have unsteady --</p> <p>7 a steady gait in that situation?</p> <p>8 A. I don't know how to explain unsteady. There's</p> <p>9 a lot of different degrees of unsteady gait and different</p> <p>10 degrees of ambulation and different degrees of assistive</p> <p>11 device necessities. I don't know how to explain that to</p> <p>12 you.</p> <p>13 Q. How would you --</p> <p>14 A. I mean, from a nursing standpoint, an unsteady</p> <p>15 gait is an abnormal gait.</p> <p>16 Q. And you would make the determination that</p> <p>17 anybody who has an abnormal gait would be evaluated for</p> <p>18 further --</p> <p>19 A. There would be further questions asked, yes.</p> <p>20 Q. And would you be the person to ask those</p> <p>21 questions?</p> <p>22 A. If they call for an MSA, yes, I would.</p> <p>23 Q. And would the MSA be the ultimate one to make a</p> <p>24 judgment on that?</p> <p>25 A. The MSA would ask further information.</p>

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<p style="text-align: right;">Page 50</p> <p>1 A. By themselves. Get on and off the bed safely</p> <p>2 without help.</p> <p>3 Q. Would you ever help donors on a --</p> <p>4 A. No. We're not permitted to help donors on or</p> <p>5 off the bed or in and out the door or -- no.</p> <p>6 Q. So based on what I'm seeing here, if a donor is</p> <p>7 able to transfer to a donor bed without help, without</p> <p>8 assistance --</p> <p>9 A. Safely and without help.</p> <p>10 Q. Safely and without help.</p> <p>11 A. Safety is a big thing at CSL.</p> <p>12 Q. If they met all other criteria, they should be</p> <p>13 able to donate?</p> <p>14 A. It would, again, depend on the case-by-case</p> <p>15 basis, because if we're called for a reason and we</p> <p>16 interview and things come up in the interview, then more</p> <p>17 information may be required.</p> <p>18 Q. Right. If they meet all other criteria and can</p> <p>19 transfer to the donor bed without assistance, would they</p> <p>20 be able to donate, if they meet all the other criteria?</p> <p>21 A. If no further information was required.</p> <p>22 Q. So the answer is yes?</p> <p>23 A. No. That's not what I said. I said if no</p> <p>24 further information was -- you want me to say yes or no</p> <p>25 on a yes or no. Yes or no. It's -- it's a case-by-case</p>	<p style="text-align: right;">Page 51</p> <p>1 process.</p> <p>2 If we pull somebody in the booth because</p> <p>3 they have an unsteady gait or they're walking with</p> <p>4 something and something comes up in the question process</p> <p>5 and we need more information for clarification, then, no,</p> <p>6 we're not going to let them donate till we get more</p> <p>7 information.</p> <p>8 Q. And after you've gotten that more</p> <p>9 information --</p> <p>10 A. If everything comes back okay, then, yes, they</p> <p>11 would be able to donate.</p> <p>12 Q. Understood.</p> <p>13 MS. DAVIS: I think I'd like to take a</p> <p>14 short break --</p> <p>15 THE WITNESS: So would I.</p> <p>16 MS. DAVIS: Okay. Good. Off the record.</p> <p>17 (Break taken from 11:59 a.m. to 12:20 p.m.)</p> <p>18 Q. (By Ms. Davis) Ms. Mailey, have you ever</p> <p>19 participated in Americans with Disabilities Act or ADA</p> <p>20 training?</p> <p>21 A. A what?</p> <p>22 Q. Have you ever participated in Americans with</p> <p>23 Disabilities Act or ADA, some people call it, training?</p> <p>24 A. I don't remember.</p> <p>25 Q. Have you ever had any kind of training about</p>
<p style="text-align: right;">Page 52</p> <p>1 avoiding disability discrimination?</p> <p>2 A. I'm -- I don't remember. I'm sure I have at</p> <p>3 some point, but I don't remember.</p> <p>4 Q. You -- you -- you say you're sure you have.</p> <p>5 Can you tell me more about the training you may have</p> <p>6 received --</p> <p>7 A. I don't remember.</p> <p>8 Q. Who may have conducted the training that you</p> <p>9 are sure you may have had in the past?</p> <p>10 A. I don't remember.</p> <p>11 Q. Was there any documentation confirming that you</p> <p>12 would have attended a training?</p> <p>13 A. I don't have any documentation, so I don't</p> <p>14 know.</p> <p>15 Q. Have you ever received any training on how to</p> <p>16 interact with people with disabilities?</p> <p>17 A. No.</p> <p>18 Q. Did you know that you weren't supposed to</p> <p>19 discriminate against people with disabilities?</p> <p>20 A. I don't discriminate against people with</p> <p>21 disabilities.</p> <p>22 Q. Did you know that you were not supposed to?</p> <p>23 A. I know you're not supposed to discriminate</p> <p>24 anybody for any reason.</p> <p>25 Q. And how do you know that?</p>	<p style="text-align: right;">Page 53</p> <p>1 A. I'm an adult, and I know that. I was raised</p> <p>2 that way.</p> <p>3 Q. What kinds of things were you raised to not do</p> <p>4 in terms of discrimination?</p> <p>5 A. I was not raised to even look at someone with a</p> <p>6 disability any different than I would look at anybody</p> <p>7 else.</p> <p>8 Q. And in your job as an MSA, were you required to</p> <p>9 look at people with disabilities differently than anyone</p> <p>10 else?</p> <p>11 A. It would depend on the disability. I mean, a</p> <p>12 seizure disorder person can't donate. So some</p> <p>13 disabilities would defer a donor.</p> <p>14 Q. Was there any internal policies at CSL Plasma</p> <p>15 about disability discrimination?</p> <p>16 A. I don't remember.</p> <p>17 Q. Are there other SOPs about screening donors</p> <p>18 other than the medical staff reference that we have</p> <p>19 already discussed?</p> <p>20 A. If I remember correctly, there are a lot of</p> <p>21 SOPs. I don't remember.</p> <p>22 Q. Are there any SOPs about deferring donors?</p> <p>23 A. I'm sure there are.</p> <p>24 Q. Do you recall what those would have been</p> <p>25 called?</p>



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<p style="text-align: right;">Page 58</p> <p>1 Q. What did the donor say over the phone?</p> <p>2 A. I don't remember exactly.</p> <p>3 Q. How did you know it was a physical threat?</p> <p>4 A. Because he threatened to do bodily damage.</p> <p>5 Q. And what did he say?</p> <p>6 A. I don't remember the exact conversation. I</p> <p>7 just remember being extremely upset and getting a</p> <p>8 manager.</p> <p>9 Q. How did you know that he threatened bodily</p> <p>10 damage?</p> <p>11 A. Because I was on the phone, and he threatened</p> <p>12 me.</p> <p>13 Q. And how did you know it was a physical threat?</p> <p>14 MS. WILLING: Counsel, objection. You've</p> <p>15 asked the question like three times now. She's answered.</p> <p>16 Q. (By Ms. Davis) I'm going to ask you again:</p> <p>17 How did you know it was a physical threat?</p> <p>18 A. Because he threatened to hurt me on the phone.</p> <p>19 Q. And you spoke with a manager after that</p> <p>20 happened; is that correct?</p> <p>21 A. Yes.</p> <p>22 Q. Who was the manager that you spoke with --</p> <p>23 A. I don't remember.</p> <p>24 Q. Can you think of any other examples?</p> <p>25 A. Yes. I was almost physically attacked in</p>	<p style="text-align: right;">Page 59</p> <p>1 the -- in the MSA room.</p> <p>2 Q. What happened in that incident?</p> <p>3 A. She charged at me and almost hit me while I was</p> <p>4 typing on the computer.</p> <p>5 Q. What did you do in reaction?</p> <p>6 A. I screamed.</p> <p>7 Q. Did somebody hear you scream?</p> <p>8 A. Yes. They came to help.</p> <p>9 Q. And what did they do to that donor?</p> <p>10 A. She was escorted out of the building and</p> <p>11 permanently deferred.</p> <p>12 Q. And did a manager get involved in that example?</p> <p>13 A. Yes.</p> <p>14 Q. What manager --</p> <p>15 A. I don't remember.</p> <p>16 Q. -- was involved? What did the manager do after</p> <p>17 that?</p> <p>18 A. The donor was permanently deferred.</p> <p>19 Q. Did the manager call to tell the donor they</p> <p>20 were permanently --</p> <p>21 A. I don't remember.</p> <p>22 Q. -- deferred? Did you call the police in that</p> <p>23 instance?</p> <p>24 A. I -- I don't know. I don't remember if -- I</p> <p>25 don't remember if they were going to call. I think they</p>
<p style="text-align: right;">Page 60</p> <p>1 were going to call, but she left the center. She didn't</p> <p>2 make contact.</p> <p>3 Q. She did make contact?</p> <p>4 A. She didn't --</p> <p>5 Q. She didn't.</p> <p>6 A. -- make contact with my -- with me.</p> <p>7 Q. Do you remember who came --</p> <p>8 A. I don't.</p> <p>9 Q. -- over once they heard you scream?</p> <p>10 A. I don't. That was a blur. I don't.</p> <p>11 Q. Were there other times that you were physically</p> <p>12 threatened?</p> <p>13 A. No. Usually it was just -- a lot of the staff</p> <p>14 would get cussed out pretty severely when someone was</p> <p>15 told they couldn't donate, or slam doors, knock over</p> <p>16 the -- I don't remember what those things are called when</p> <p>17 you have the queue line and you have those metal posts</p> <p>18 with the ropes. They'd knock those over on their way</p> <p>19 out. Just aggressive and violent behaviors.</p> <p>20 Q. How often would that happen?</p> <p>21 A. Oh, it's pretty frequent. Donors get told they</p> <p>22 can't donate. They get mad. Donor has a tattoo that's</p> <p>23 not old enough. Or donor comes back after being gone for</p> <p>24 a while, and they've gotten a tattoo since, and they</p> <p>25 can't -- you can't donate unless the tattoo is 12 months</p>	<p style="text-align: right;">Page 61</p> <p>1 old. Then -- there's all kinds of things that trigger</p> <p>2 donors to get verbally abusive.</p> <p>3 Q. And those donors that were threatening would</p> <p>4 cuss frequently?</p> <p>5 A. They become verbally abusive. I can't remember</p> <p>6 everything every donor ever said. It could get ugly.</p> <p>7 Q. Are there any other times that someone</p> <p>8 threatened physical violence?</p> <p>9 A. At the plasma center?</p> <p>10 Q. Correct.</p> <p>11 A. No. Those are the only two. I mean, I was --</p> <p>12 there have been threats but not necessarily physical</p> <p>13 harm.</p> <p>14 Q. And did you get training on how to react to</p> <p>15 these kinds of threats?</p> <p>16 A. I don't think anybody trains you for how to</p> <p>17 take a physical threat or a threat at all. I call the</p> <p>18 management. When things get out of hand, I call the</p> <p>19 management. That's why they're there.</p> <p>20 Q. And was that what you were instructed to do?</p> <p>21 A. Yes, we call management.</p> <p>22 Q. The management that you would call, would that</p> <p>23 be Rey Vargas?</p> <p>24 A. It would be whatever manager was at the center</p> <p>25 that day, different managers. They work different</p>

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62 to 65

<p style="text-align: right;">Page 62</p> <p>1 shifts. It's the manager. 2 Q. And I'm sorry. I'm going to have to ask you 3 again, because I may not remember. But the managers at 4 the time -- 5 A. The ones I can remember are Rey Vargas, Nola 6 Baker, and Dennis Thomas. 7 Q. Okay. 8 A. We also had the quality control people, but 9 they were not managers. We had another main manager. I 10 can't remember. We had two while I was there. I don't 11 remember which one was there. I don't remember their 12 names. 13 Q. And the quality control, who were they? 14 A. They weren't managers. 15 Q. Where did the quality control individuals sit? 16 A. In their offices. They weren't managers. They 17 just worked in quality control. 18 Q. Did they ever interact with donors? 19 A. No. I think the only one that -- they would 20 help on the donor floor when we're backed up. That's it. 21 Not the screening process, just donor floor. 22 Q. Did you ever have to call upon the quality 23 control staff? 24 A. No. 25 Q. So --</p>	<p style="text-align: right;">Page 63</p> <p>1 A. They weren't managers. 2 Q. You didn't go to them with questions? 3 A. We went to them with -- when tattoo stuff came 4 up, because they'd have to pull the plasma that was 5 related to the donor. 6 Q. Did you enjoy working at CSL Plasma? 7 A. I did the time I was there. 8 Q. And were plasma donors challenging patients? 9 A. No, not all the time. Some of them were a 10 blast. I mean, you get to know them. They're like 11 family. They're there twice a week every week. They're 12 there. They're -- you know them. You get to know their 13 faces, their birthdays. It's not always bad. 14 Q. Do -- do donors express dissatisfaction 15 sometimes to you with their experience at CSL Plasma? 16 A. Oh, I'm sure they did. 17 Q. Why would they express their dissatisfaction? 18 A. I don't know. Probably come up in 19 conversation. I don't recall exactly. I don't even know 20 an instance where someone did, so I don't know. I'm sure 21 in conversation somebody might have said something 22 happened last week. I don't know. 23 Q. Did anybody ever ask to speak with a 24 supervisor, your supervisor, and they ask you -- sorry. 25 Did anybody ever ask you to speak with your supervisor?</p>
<p style="text-align: right;">Page 64</p> <p>1 A. I'm sure they did, but I couldn't remember an 2 incident. I mean, it's a while back. I don't remember. 3 Q. Any times that somebody told you that they were 4 going to call corporate or anything like that? 5 A. Yeah. We got threats like that all the time. 6 Uh-huh. 7 Q. And what would you do when somebody said they 8 were going to call corporate? 9 A. Nothing. 10 Q. Were -- 11 A. If they were being verbally aggressive or 12 abusive, we would get management. Otherwise, that -- 13 that's well within their rights. They can call 14 corporate. 15 Q. Were you worried when they said they -- 16 A. No. 17 Q. -- were going to call corporate? Would you 18 be -- would you be scared when they said they were going 19 to call corporate? 20 A. No. I did my job. So, no, I was not scared. 21 Q. Plasma donors would get angry sometimes, 22 correct? 23 A. Yes. 24 Q. And how could you tell that they were angry? 25 A. There's different degrees of anger. There's</p>	<p style="text-align: right;">Page 65</p> <p>1 some that just got mad. And then there's some that 2 became verbally abusive and aggressive. There's some 3 that became physically aggressive. So there's different 4 degrees of anger. There's different degrees of behavior. 5 Q. And if somebody became verbally aggressive, 6 what would they do? 7 A. First, we would try to instruct them to calm 8 down. And if they didn't, they would be -- management 9 would come out. And then management would take over. 10 Nine times out of ten, if a donor became verbally 11 aggressive or abusive, they were permanently deferred. 12 Q. And if management didn't come out or wasn't 13 called, does that mean the person wasn't being verbally 14 aggressive? 15 A. Probably. 16 Q. If somebody was being verbally aggressive, you 17 would call the manager? 18 A. Yes. 19 Q. Is that correct? 20 A. Uh-huh. 21 Q. And would you stay with the donor and the 22 manager -- 23 A. No. 24 Q. -- while they -- 25 A. If I was the one being verbally attacked, no, I</p>

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66 to 69

<p style="text-align: right;">Page 66</p> <p>1 don't stay. No.</p> <p>2 Q. You were able to leave and remove yourself from</p> <p>3 the --</p> <p>4 A. Manager takes over.</p> <p>5 Q. -- situation; is that correct? Sorry. Let me</p> <p>6 just finish the question. So you were able to leave and</p> <p>7 remove yourself from the --</p> <p>8 A. Yes.</p> <p>9 Q. -- situation, correct? And would there be</p> <p>10 documentation of this -- this aggression or this verbal</p> <p>11 aggression?</p> <p>12 A. The manager typically puts in a note.</p> <p>13 Q. And would you ever be the one that was required</p> <p>14 to --</p> <p>15 A. I know I put in notes on donors, yeah.</p> <p>16 Q. What kinds of notes would you put in?</p> <p>17 A. Well, it would depend on the situation. It</p> <p>18 would be a note explaining the situation, if I put it in.</p> <p>19 Generally when the managers took over, it becomes a</p> <p>20 management problem, not a medical problem.</p> <p>21 Q. Would you be the one to tell potential donors</p> <p>22 if they were deferred?</p> <p>23 A. If it was for a medical purpose. For a</p> <p>24 permanent deferral? No.</p> <p>25 Q. What about for a temporary deferral?</p>	<p style="text-align: right;">Page 67</p> <p>1 A. It would depend on the situation again.</p> <p>2 It's -- every -- it's a case-by-case. Would depend on</p> <p>3 what the deferral was for.</p> <p>4 Q. If it was a medical deferral and it was your</p> <p>5 donor, would you be the MSA that would tell --</p> <p>6 A. They would be informed of a temp or permanent.</p> <p>7 Q. I'm sorry. I am going to finish the question.</p> <p>8 I know it's difficult. If you were the individual that</p> <p>9 was assessing the donor, you were the MSA, and it was a</p> <p>10 temporary deferral, would you be the individual to tell</p> <p>11 the donor about the deferral?</p> <p>12 A. If I was deferring a donor for either the day</p> <p>13 or it was going to be a permanent medical deferral, I</p> <p>14 would be the one, if it was a medical deferral. And it</p> <p>15 would be me or another MSA.</p> <p>16 Q. And what would you tell them when you were</p> <p>17 deferring them for the day?</p> <p>18 A. We would explain the reason for the deferral</p> <p>19 and what they needed to get the deferral lifted.</p> <p>20 Q. You would give them information about what they</p> <p>21 could do to get the deferral lifted?</p> <p>22 A. If it was something that could be lifted, yes,</p> <p>23 if it wasn't a permanent. If it was a temporary deferral</p> <p>24 that just required either more information or the action</p> <p>25 of a donor to do something to get it lifted, then it</p>
<p style="text-align: right;">Page 68</p> <p>1 would be lifted.</p> <p>2 Q. What actions would the donor need to do?</p> <p>3 A. It would depend on what they were deferred for.</p> <p>4 Q. What is one example of something that the donor</p> <p>5 could do to get the temporary deferral lifted?</p> <p>6 A. If a donor had a -- if they stated that they</p> <p>7 had a fracture, they couldn't remember when the fracture</p> <p>8 was, they would have to go to their doctor and get a</p> <p>9 letter stating from their doctor that it's okay to</p> <p>10 donate.</p> <p>11 Q. Okay. What else might a donor need to do to</p> <p>12 get the temporary deferral lifted?</p> <p>13 A. It would depend on the case. I can't sit here</p> <p>14 and come up with cases and cases. I don't know. There's</p> <p>15 a lot of different things. Donors can get more</p> <p>16 information on to get deferrals lifted.</p> <p>17 Q. I'm asking you to think of what you can recall.</p> <p>18 If there are other examples of something a donor can do</p> <p>19 to get the temporary deferral lifted, can you recall what</p> <p>20 that might be?</p> <p>21 A. Typically MSAs would ask for letters from</p> <p>22 doctors for different reasons.</p> <p>23 Q. Did you ever give instructions to a potential</p> <p>24 donor to drink more water?</p> <p>25 A. If something came back in their screening that</p>	<p style="text-align: right;">Page 69</p> <p>1 indicated that they should probably drink more water,</p> <p>2 yes, I'm sure we would educate them to drink more water.</p> <p>3 Q. Did you give other pieces of education to</p> <p>4 potential donors about what they could do to get their</p> <p>5 temporary deferral lifted?</p> <p>6 A. Commonly in the new donor process, yes.</p> <p>7 Q. What are some of those?</p> <p>8 A. Well, they have to eat before they donate.</p> <p>9 They need to be well hydrated to donate. I mean, if</p> <p>10 somebody comes in and their iron and stuff is low in the</p> <p>11 screening process, we're going to instruct them on foods</p> <p>12 to eat to boost their iron.</p> <p>13 Q. For permanent deferrals, you were also the</p> <p>14 person that would potentially tell them that they were</p> <p>15 permanently deferred if it was a medical reason; is that</p> <p>16 correct?</p> <p>17 A. For a medical reason, yes.</p> <p>18 Q. And what would you tell them about the</p> <p>19 permanent deferral?</p> <p>20 A. Would depend on what the deferral was for.</p> <p>21 Q. Would you tell them why the deferral was -- had</p> <p>22 occurred?</p> <p>23 A. Yes. If it was a medical deferral that I</p> <p>24 applied, yes.</p> <p>25 Q. And did you explain to them that the deferral</p>



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74 to 77

<p style="text-align: right;">Page 74</p> <p>1 nonmedical reasons?</p> <p>2 A. We -- I don't -- I never deferred a donor for a</p> <p>3 nonmedical reason.</p> <p>4 Q. Were you authorized to do so?</p> <p>5 A. I don't recall.</p> <p>6 Q. Aside from your employment at CSL Plasma, have</p> <p>7 you ever been threatened while at work?</p> <p>8 A. Oh, yes.</p> <p>9 Q. When was that?</p> <p>10 A. Well, how does that pertain to this? That's</p> <p>11 personal.</p> <p>12 Q. I'm going to ask the question again. Had you</p> <p>13 ever been threatened in the workplace?</p> <p>14 A. Yes. I have been threatened in the workplace</p> <p>15 before other than at the plasma center.</p> <p>16 Q. Have you been threatened in the workplace since</p> <p>17 then?</p> <p>18 A. Yes.</p> <p>19 Q. Where did that happen?</p> <p>20 A. That is personal.</p> <p>21 Q. I'm going to ask the question again. Where did</p> <p>22 the threats in the workplace --</p> <p>23 A. At the Nueces County Jail.</p> <p>24 Q. What -- what happened?</p> <p>25 A. I am not at liberty -- I'm not discussing that.</p>	<p style="text-align: right;">Page 75</p> <p>1 Q. I'm going to ask the question again. What</p> <p>2 happened in the Nueces County Jail?</p> <p>3 A. I am not answering. That has nothing to do</p> <p>4 with this. There was a case involved, and I'm not</p> <p>5 answering that.</p> <p>6 MS. DAVIS: Let the record show that the</p> <p>7 answer was nonresponsive.</p> <p>8 Q. (By Ms. Davis) Setting aside the Nueces County</p> <p>9 Jail example, were there other threats made to you in the</p> <p>10 workplace?</p> <p>11 A. After CSL? No.</p> <p>12 Q. And what about before CSL --</p> <p>13 A. Yes.</p> <p>14 Q. -- were there -- and when did those occur?</p> <p>15 A. Had a mentally unstable son of a patient in</p> <p>16 home health that attacked me on the porch.</p> <p>17 Q. Did you call the police?</p> <p>18 A. I went to the police.</p> <p>19 Q. And was a police report made about that?</p> <p>20 A. I'm sure there was. But that was many, many</p> <p>21 years ago, and I don't remember.</p> <p>22 Q. And did you have to tell your supervisor when</p> <p>23 that happened?</p> <p>24 A. I called my supervisor.</p> <p>25 Q. And did you have to make any documentations</p>
<p style="text-align: right;">Page 76</p> <p>1 about that threat?</p> <p>2 A. I don't remember.</p> <p>3 MS. DAVIS: I'd like to take just a short</p> <p>4 break, if that's okay with you. It will be short. Thank</p> <p>5 you. Off the record.</p> <p>6 (Break taken from 12:51 p.m. to 12:56 p.m.)</p> <p>7 Q. (By Ms. Davis) Ms. Mailey, do you know that</p> <p>8 the lawsuit involves a donor named Mark Silguero?</p> <p>9 A. That's what it was on the subpoena.</p> <p>10 Q. Do you remember Mr. Silguero?</p> <p>11 A. A little, not a lot.</p> <p>12 Q. What do you remember about him?</p> <p>13 A. He got mad because I didn't let him donate that</p> <p>14 day.</p> <p>15 Q. How did you know he was mad?</p> <p>16 A. Because he came -- became verbally aggressive</p> <p>17 and slammed the door and threatened. I called a manager.</p> <p>18 Q. What job duty did you have on the day that you</p> <p>19 assessed Mr. Silguero?</p> <p>20 A. I can't remember who or why. But I know that</p> <p>21 there was -- something came up about his -- the way he</p> <p>22 was walking or the limp or something. So we brought him</p> <p>23 in to ask him some questions. And he hadn't been to the</p> <p>24 center in a while.</p> <p>25 Q. Did you ask him those questions?</p>	<p style="text-align: right;">Page 77</p> <p>1 A. Uh-huh.</p> <p>2 Q. What questions did you ask?</p> <p>3 A. I don't remember exactly. I know I asked him</p> <p>4 about his -- the way he was walking and the cane, because</p> <p>5 he had a really severe limp. And he had said something</p> <p>6 about needing surgery or something.</p> <p>7 And that's where the conversation kind of</p> <p>8 went to: If you're pending surgery, you can't donate</p> <p>9 plasma. You need a note from your doctor.</p> <p>10 Q. Did you tell him that he needed a note --</p> <p>11 A. Yes.</p> <p>12 Q. -- from his doctor?</p> <p>13 A. Nobody who's pending surgery or had surgery can</p> <p>14 donate plasma.</p> <p>15 Q. If there's no surgery that has been</p> <p>16 scheduled --</p> <p>17 A. We would still need clarification from the</p> <p>18 patient's doctor, because we don't know how old the</p> <p>19 injury is, what the injury is, what's going on. We</p> <p>20 need -- basically the patient's doctor needs to say it's</p> <p>21 okay.</p> <p>22 Q. And what would the note from the doctor have</p> <p>23 been required to say?</p> <p>24 A. That would have been up to the doctors</p> <p>25 basically, whether or not the doctor felt it was okay for</p>

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<p style="text-align: right;">Page 78</p> <p>1 the donor to donate.</p> <p>2 Q. CSL Plasma needed something from his doctor</p> <p>3 that said he was okay to donate?</p> <p>4 A. Yes, because he made a statement about needing</p> <p>5 surgery.</p> <p>6 Q. Did you tell them that once he got the note</p> <p>7 from his doctor, he would be able to donate plasma?</p> <p>8 A. There was no guarantee he would be able. It</p> <p>9 would depend on what the note said. So, no. It was</p> <p>10 basically he made his comment about surgery. I asked. I</p> <p>11 don't remember exactly what I asked.</p> <p>12 He needs a note from the doctor, because</p> <p>13 we need to know what kind of -- you know, is it an</p> <p>14 injury? Is it new? Is it a fracture? What is -- I</p> <p>15 mean, what is it?</p> <p>16 So when I told him he needed a note from</p> <p>17 his doctor, he became angry and started cursing. I</p> <p>18 called a manager. Dennis took over.</p> <p>19 Q. And Dennis came into the room?</p> <p>20 A. We weren't in a room. We were at the donor --</p> <p>21 at the end of the donor booths, in a booth.</p> <p>22 Q. Dennis came to the booth?</p> <p>23 A. Uh-huh.</p> <p>24 Q. And did you leave at that point?</p> <p>25 A. I stepped off to the new donor area.</p>	<p style="text-align: right;">Page 79</p> <p>1 Q. And you had called Dennis to come to the</p> <p>2 booth --</p> <p>3 A. Yes. The patient was verbally abusive. So,</p> <p>4 yes, I called a manager.</p> <p>5 Q. And what was he saying that made you think he</p> <p>6 was being verbally abusive?</p> <p>7 A. He was cursing.</p> <p>8 Q. What else?</p> <p>9 A. He made a threatening statement at one point.</p> <p>10 I don't remember exactly what the threat was. But Dennis</p> <p>11 took over, so I left.</p> <p>12 Q. What else?</p> <p>13 A. I don't recall.</p> <p>14 Q. You deferred him because he needed a note from</p> <p>15 his doctor; is that --</p> <p>16 A. I don't believe I deferred him.</p> <p>17 Q. Who deferred him?</p> <p>18 A. I believe Dennis Thomas is the one that</p> <p>19 deferred the donor.</p> <p>20 Q. Did you tell --</p> <p>21 A. I told him he couldn't donate that day without</p> <p>22 a letter from his doctor. I didn't apply any deferrals,</p> <p>23 not to my knowledge.</p> <p>24 Q. What do you mean you didn't apply any</p> <p>25 deferrals?</p>
<p style="text-align: right;">Page 80</p> <p>1 A. I didn't apply a deferral in the system on the</p> <p>2 donor. Dennis Thomas deferred the donor.</p> <p>3 Q. Did you tell the donor that he could not donate</p> <p>4 that day?</p> <p>5 A. That day.</p> <p>6 Q. What is that called if you tell a donor --</p> <p>7 A. I didn't apply a deferral. He just needed to</p> <p>8 bring a note from the doctor.</p> <p>9 Q. If someone is not allowed to donate that day,</p> <p>10 is that not called a deferral?</p> <p>11 A. Yes. It would have been a deferral had it not</p> <p>12 escalated into a management situation. It escalated into</p> <p>13 a management situation. Therefore, the manager took</p> <p>14 over, and it was not a medical situation any longer.</p> <p>15 Q. Had you deferred him temporarily for a medical</p> <p>16 reason?</p> <p>17 A. I hadn't even gotten to the deferral point. I</p> <p>18 told the donor that we needed a note from his doctor, and</p> <p>19 he immediately became verbally aggressive. So I called</p> <p>20 for management, and I stepped away, and Dennis took over.</p> <p>21 I didn't even get to explain anything else</p> <p>22 other than we need a note from your doctor. No donor can</p> <p>23 say anything surgery and not us want clarification.</p> <p>24 Q. Were you sitting down when you had that</p> <p>25 conversation with him?</p>	<p style="text-align: right;">Page 81</p> <p>1 A. No. He was standing here. There's a counter</p> <p>2 here, and I was standing here.</p> <p>3 Q. You were standing on the other side of the</p> <p>4 counter?</p> <p>5 A. Yeah. The donor comes in the door. I'm on the</p> <p>6 little hallway where all of us move around. And there's</p> <p>7 a counter, and I'm on this side of the counter.</p> <p>8 Q. I -- I haven't been to the CSL Plasma, so I</p> <p>9 can't imagine it exactly. So you're on one side of the</p> <p>10 counter, and he's on the other side. And you had been</p> <p>11 called to that booth --</p> <p>12 A. I don't remember exactly how it happened. I</p> <p>13 know there was -- I think I was called regarding his --</p> <p>14 the severe limp he had and the cane. I think one of the</p> <p>15 screeners had called me. I don't remember exactly why.</p> <p>16 I don't remember exactly how it went. I</p> <p>17 know that when I saw him ambulating down the hallway, it</p> <p>18 was pretty severe limp.</p> <p>19 Q. Did you ask him at all about his limp?</p> <p>20 A. That's what triggered the whole surgery. I</p> <p>21 can't remember. I think he said it was something about</p> <p>22 his knee and that he was needing surgery.</p> <p>23 Q. And did you look at his previous history, his</p> <p>24 previous donor history?</p> <p>25 A. No. We didn't even get to that point.</p>

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<p style="text-align: right;">Page 82</p> <p>1 Q. Do you remember him before that visit?</p> <p>2 A. No.</p> <p>3 Q. Did you ask the medical director about the --</p> <p>4 the upcoming --</p> <p>5 A. No, there was no need.</p> <p>6 Q. -- surgery? Did you ask the medical director</p> <p>7 about the upcoming surgery?</p> <p>8 A. No, there was no need. The clarification</p> <p>9 needed to come from the patient's doctor.</p> <p>10 Q. Did you make the determination that the</p> <p>11 clarification needed to come from --</p> <p>12 A. I told the donor he needed a letter from his</p> <p>13 doctor. So, yes, I told the patient he needed a letter</p> <p>14 from his doctor.</p> <p>15 Q. Is there a phone in the booth that you were</p> <p>16 able to use to call Dennis?</p> <p>17 A. I don't remember.</p> <p>18 Q. How did you call Dennis?</p> <p>19 A. I think I yelled for a manager from one of the</p> <p>20 girls and they called him. I don't remember.</p> <p>21 Q. So you call --</p> <p>22 A. It's been a while. I don't remember. I</p> <p>23 requested a manager.</p> <p>24 Q. And do you remember if there was a phone --</p> <p>25 A. I don't remember.</p>	<p style="text-align: right;">Page 83</p> <p>1 Q. -- that you would have been able to use? I'm</p> <p>2 going to --</p> <p>3 A. I don't remember.</p> <p>4 Q. Let me finish the question, and then you can</p> <p>5 answer. Was there a phone in the booth that you can</p> <p>6 remember?</p> <p>7 A. I don't remember.</p> <p>8 Q. Your recollection is that you may have yelled</p> <p>9 for --</p> <p>10 A. Not yelled, but there's girls all down there.</p> <p>11 Q. Called out?</p> <p>12 A. I asked for a manager. I just don't remember</p> <p>13 how exactly the manager got to get there. I know it was</p> <p>14 Dennis.</p> <p>15 Q. And who would have been the -- the other people</p> <p>16 that would have heard your call? You said you -- it</p> <p>17 was -- you called --</p> <p>18 A. There was a bunch of donor booths.</p> <p>19 Q. -- girls?</p> <p>20 A. There's a bunch of donor booths, everybody that</p> <p>21 was screening.</p> <p>22 Q. And what -- what kind of staff were those?</p> <p>23 Were they also MSAs?</p> <p>24 A. No.</p> <p>25 Q. No?</p>
<p style="text-align: right;">Page 84</p> <p>1 A. They were the screeners in the -- I don't</p> <p>2 remember what their title was.</p> <p>3 Q. Do you remember who was talking to Mr. Silguero</p> <p>4 before you?</p> <p>5 A. No.</p> <p>6 Q. Do you remember who called you --</p> <p>7 A. No.</p> <p>8 Q. -- for additional -- okay. I --</p> <p>9 A. I know. But it's like I've answered these</p> <p>10 questions already, and you keep asking the same ones, and</p> <p>11 it's just --</p> <p>12 Q. I do have to finish --</p> <p>13 A. Okay.</p> <p>14 Q. -- my question. Do you remember who called you</p> <p>15 to address Mr. Silguero about his gait?</p> <p>16 A. No.</p> <p>17 Q. Do you know the job title of that person that</p> <p>18 would have called you?</p> <p>19 A. No. I don't remember what they were called.</p> <p>20 Q. How close were the other booths to the booth</p> <p>21 that you were in?</p> <p>22 A. I don't remember if somebody was right next to</p> <p>23 me, but the booths are touching.</p> <p>24 Q. Are they side by side?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 85</p> <p>1 Q. Did anybody else hear Mr. Silguero's comments</p> <p>2 to you?</p> <p>3 A. I don't remember. I don't know.</p> <p>4 Q. Did you write down the comments that he made to</p> <p>5 you?</p> <p>6 A. No. I told my manager. My manager took over.</p> <p>7 Q. Beyond telling your manager, did you have</p> <p>8 any -- did you make any further documentation of</p> <p>9 Mr. Silguero's interaction with you?</p> <p>10 A. No. I was very upset. I walked away.</p> <p>11 Q. Did anyone else say that he had threatened</p> <p>12 them?</p> <p>13 A. I don't know.</p> <p>14 Q. So the only thing that you are aware of --</p> <p>15 aware of is the statement that he made to you?</p> <p>16 A. He was still yelling at Dennis while I was over</p> <p>17 in the new donor area. Could I hear exactly what he was</p> <p>18 yelling at Dennis about? No.</p> <p>19 Q. Did he say that he had a weapon?</p> <p>20 A. No.</p> <p>21 Q. And did he make any physical threats?</p> <p>22 A. I don't recall. I just remember him being</p> <p>23 verbally aggressive and cursing quite a bit.</p> <p>24 Q. Did you call the police?</p> <p>25 A. No. The manager took over.</p>

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<p style="text-align: right;">Page 90</p> <p>1 must speak to this donor prior to his next donation. MSA 2 MM told donor he would be unable to donate due to using a 3 cane and walking with a limp. He told her that she would 4 regret this and left, DT, January 1st -- or January 2nd, 5 2015.</p> <p>6 Are you MSA MM --</p> <p>7 A. Yeah.</p> <p>8 Q. -- in this note? The note says that you told 9 the donor he would be unable to donate due to using a 10 cane and walking with a limp.</p> <p>11 A. That's not my documentation. That's Dennis's 12 documentation.</p> <p>13 Q. Do you disagree with this documentation that 14 says that he was unable to donate due to using a cane and 15 walking with a limp?</p> <p>16 A. Yeah, because he needed a note from the doctor.</p> <p>17 Q. Do you know why Dennis would have put the cane 18 and walking with a limp?</p> <p>19 MS. WILLING: Objection, speculation.</p> <p>20 That's not her note.</p> <p>21 Q. (By Ms. Davis) You can go ahead and answer.</p> <p>22 A. That's not my documentation.</p> <p>23 Q. Do you remember Mr. Silguero saying you would 24 regret this?</p> <p>25 A. Oh, yes.</p>	<p style="text-align: right;">Page 91</p> <p>1 Q. Did you defer him because he used a cane?</p> <p>2 A. No.</p> <p>3 Q. Did you defer him because he walked with a 4 limp?</p> <p>5 A. No.</p> <p>6 Q. Did you defer him because he could not transfer 7 onto the donor bed?</p> <p>8 A. No. That hadn't even been assessed yet.</p> <p>9 Q. Would you have had access to Mr. -- 10 Mr. Silguero's records while you were talking with him?</p> <p>11 A. I don't remember if there was a computer in 12 that booth.</p> <p>13 Q. Looking at line 2, it states, 1/3/15, donor 14 PR'd for threatening staff, TMB, 1/3/15.</p> <p>15 Do you know what TMB is?</p> <p>16 A. No. Looks like somebody's initials.</p> <p>17 Q. Do you know who that would be?</p> <p>18 A. No.</p> <p>19 Q. Do you think it would be somebody named Tammy 20 Brown?</p> <p>21 A. Possibly.</p> <p>22 Q. Do you remember somebody named Tammy Brown?</p> <p>23 A. I remember a Tammy.</p> <p>24 Q. The first note that we talked about on -- 25 starting on line 3 was made on January 2nd, 2015. The</p>
<p style="text-align: right;">Page 92</p> <p>1 second note was made on January 3rd, 2015. Did you do 2 anything between those two dates in reference to 3 Mr. Silguero?</p> <p>4 A. I don't -- no. There's nothing documented, not 5 that I remember.</p> <p>6 Q. Did you talk to Dennis after Mr. Silguero left?</p> <p>7 A. I don't remember.</p> <p>8 Q. Did you talk to any staff member about 9 Mr. Silguero after he left?</p> <p>10 A. I don't remember.</p> <p>11 Q. On January 3rd, 2015, did you talk to any staff 12 member about Mr. Silguero?</p> <p>13 A. I don't remember.</p> <p>14 Q. On the second line, donor PR'd for threatening 15 staff, was his interaction with you the threatening 16 staff --</p> <p>17 A. It's possible. It says you would regret this. 18 So that's a threat, so it's possible.</p> <p>19 Q. Are you aware of any other threats that he 20 made?</p> <p>21 A. I don't remember the whole conversation.</p> <p>22 Q. But are you aware of any other threats that he 23 made?</p> <p>24 A. I don't remember the whole interaction with 25 him.</p>	<p style="text-align: right;">Page 93</p> <p>1 Q. So you are unaware of any threats that were 2 made?</p> <p>3 A. I don't remember.</p> <p>4 Q. Who made the decision to PR him?</p> <p>5 A. I don't know. I would assume it would be a 6 manager.</p> <p>7 Q. Do you know if it was Dennis Thomas?</p> <p>8 A. I would assume. He was the manager that day.</p> <p>9 Q. There was a manager -- you've mentioned a 10 center manager, who it sounds like was above Dennis 11 Thomas. Would he have been involved in a decision like 12 this?</p> <p>13 A. If he was not there that day as acting manager, 14 no. Dennis Thomas was the acting manager that day. So I 15 don't know what happened the next day. I don't remember.</p> <p>16 Q. Was it -- the acting manager was whoever was 17 there that day. And if somebody was not there that day, 18 is it your testimony that they are not involved in the 19 decision?</p> <p>20 A. I don't know.</p> <p>21 Q. Are you in touch with Dennis Thomas now?</p> <p>22 A. No.</p> <p>23 Q. Do you know where he lives?</p> <p>24 A. No. Last I heard, he left the state. I don't 25 know where he went.</p>

John Nelson, M.D., Ph.D.

July 12, 2017

1

Page 1

1 IN THE UNITED STATES DISTRICT COURT

2 FOR THE SOUTHERN DISTRICT OF TEXAS

3 CORPUS CHRISTI DIVISION

4 -----  
5 MARK SILGUERO,

6 Plaintiff,

7 and File No. 2:16-CV-00361

8 AMY WOLFE,

9 Intervening Plaintiff,

10 v.

11 CSL PLASMA INC.,

12 Defendant.  
13 -----

14 DEPOSITION OF

15 JOHN NELSON, M.D., Ph.D.

16 Taken on July 12, 2017

17 Commencing at 9:00 a.m.  
18  
19  
20  
21  
22  
23

24 REPORTED BY: NANCY G. GISCH, RMR, CRR, CLR  
25

John Nelson, M.D., Ph.D.

July 12, 2017

6 to 9

<p style="text-align: right;">Page 6</p> <p>1 PROCEEDINGS</p> <p>2 JOHN NELSON, M.D., Ph.D.,</p> <p>3 duly sworn, was examined and testified as follows:</p> <p>4 EXAMINATION</p> <p>5 BY MR. EAST:</p> <p>6 Q. And, Doctor Nelson, would you state your</p> <p>7 full name for the record.</p> <p>8 A. My name is John Edward Nelson,</p> <p>9 N-E-L-S-O-N.</p> <p>10 Q. Thank you.</p> <p>11 My name is Brian East. I am a lawyer for</p> <p>12 the plaintiff -- plaintiffs in this case, Mark</p> <p>13 Silguero and Amy Wolfe.</p> <p>14 And we have not spoken before today. Is</p> <p>15 that correct?</p> <p>16 A. Yes.</p> <p>17 Q. All right. I'm going to be asking you</p> <p>18 questions here today. And the court reporter</p> <p>19 will be transcribing them. And you have taken</p> <p>20 the oath.</p> <p>21 So do you understand that your answers</p> <p>22 here today are under oath, the same as if you</p> <p>23 were testifying in court?</p> <p>24 A. Yes.</p> <p>25 Q. It is important, because we have a court</p>	<p style="text-align: right;">Page 8</p> <p>1 Q. And if you don't tell me that you don't</p> <p>2 understand, I'm going to assume that you do</p> <p>3 understand the question.</p> <p>4 Is that all right?</p> <p>5 A. Yes.</p> <p>6 Q. Tell me about your education after high</p> <p>7 school.</p> <p>8 A. After high school I attended Sauk,</p> <p>9 S-A-U-K, Valley College near Sterling, Illinois,</p> <p>10 for two years.</p> <p>11 I then transferred to the University of</p> <p>12 Illinois at Chicago Circle. And there I obtained</p> <p>13 my bachelor's in chemistry. I stayed on at the</p> <p>14 University of Illinois, at Chicago Circle, and</p> <p>15 obtained a master's in chemistry and eventually a</p> <p>16 Ph.D. in chemistry.</p> <p>17 I -- during my Ph.D. I began medical</p> <p>18 school at Rush Medical College in Chicago,</p> <p>19 Illinois. I obtained my M.D.</p> <p>20 And then for internship and residency -- I</p> <p>21 did that at Loyola University Medical Center in</p> <p>22 Maywood, Illinois.</p> <p>23 Later I did a fellowship in clinical</p> <p>24 pharmacology at Northwestern University, in</p> <p>25 Chicago, Illinois.</p>
<p style="text-align: right;">Page 7</p> <p>1 reporter, that you wait until I finish my</p> <p>2 question before you answer. And that I wait</p> <p>3 until I -- until you finish your answer before</p> <p>4 asking you another question. So I am going to</p> <p>5 try to do that as best I can.</p> <p>6 And will you agree to try to do that?</p> <p>7 A. Yes.</p> <p>8 Q. Also, because we have a court reporter,</p> <p>9 it's important that you give your answers</p> <p>10 verbally, as opposed to nodding your head or</p> <p>11 shaking it. Also, because I'm on the phone and</p> <p>12 so I won't be able to see that.</p> <p>13 And so it's important to give answers</p> <p>14 verbally and, also, not saying things like uh-huh</p> <p>15 and huh-uh, so that we make sure that your answer</p> <p>16 is accurately transcribed.</p> <p>17 Is that okay?</p> <p>18 A. Yes.</p> <p>19 Q. If at any time you need to take a break,</p> <p>20 that's fine. Just let us know. Okay?</p> <p>21 A. Yes.</p> <p>22 Q. And if you don't understand a question</p> <p>23 that I ask, will you let me know or ask me to</p> <p>24 repeat it?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 9</p> <p>1 That's the extent of my education.</p> <p>2 Q. Thank you.</p> <p>3 Tell me what year you got your medical</p> <p>4 degree.</p> <p>5 A. 1983.</p> <p>6 Q. And is that an M.D. degree?</p> <p>7 A. Yes.</p> <p>8 Q. Did you have any work experience prior</p> <p>9 to -- let's say prior to graduate school or</p> <p>10 medical school that is relevant to the plasma</p> <p>11 industry or CSL or the work you do at CSL?</p> <p>12 A. No.</p> <p>13 Q. All right. Could you tell me, in</p> <p>14 chronological order, starting with the oldest,</p> <p>15 what your work experience has been, either during</p> <p>16 medical school or after medical school?</p> <p>17 A. During medical school I continued as a</p> <p>18 graduate student assistant at the University of</p> <p>19 Illinois.</p> <p>20 After medical school I was an intern and</p> <p>21 resident at Loyola University Medical Center.</p> <p>22 Part of that was rotating at Hines VA, in Hines,</p> <p>23 Illinois, which is next door to Maywood.</p> <p>24 Following that, I was a fellow in clinical</p> <p>25 pharmacology at Northwestern University in</p>



<p style="text-align: right;">Page 10</p> <p>1 Chicago, Illinois.</p> <p>2 And then I moved back to Loyola University</p> <p>3 and Hines VA, where I was an assistant professor.</p> <p>4 In about 1997 or '98 I moved to Eli Lilly,</p> <p>5 in Indianapolis. I worked with them for two</p> <p>6 years.</p> <p>7 And then moved back to the Chicago area,</p> <p>8 where I worked for Evanston Hospital and</p> <p>9 G.D. Searle. I did that for about two years.</p> <p>10 Then I worked in private practice in the</p> <p>11 western suburbs of LaGrange and Hinsdale,</p> <p>12 Illinois. During that time I did some locum</p> <p>13 tenens work in Wisconsin, Illinois, and Indiana.</p> <p>14 And in 2000 I began working with a</p> <p>15 predecessor company of CSL. At the time it was</p> <p>16 called Nabi, N-A-B-I. It later became ZLB. And</p> <p>17 then later on was acquired by CSL.</p> <p>18 I served as a center medical director for</p> <p>19 several companies, including Nabi, around the</p> <p>20 Chicago area and northwest Indiana.</p> <p>21 In about 2005 the position of di --</p> <p>22 divisional medical director opened up. At the</p> <p>23 time the company was ZLB. And I was appointed to</p> <p>24 that position. And I've been a divisional</p> <p>25 medical director with ZLB and CSL since about</p>	<p style="text-align: right;">Page 12</p> <p>1 time.</p> <p>2 Q. You said that you were in private practice</p> <p>3 for a while in the western suburbs. What was</p> <p>4 your area of practice?</p> <p>5 A. Internal medicine.</p> <p>6 Q. And then when you were a visiting</p> <p>7 physician, was that also serving as an internal</p> <p>8 medicine doctor?</p> <p>9 A. Yes.</p> <p>10 Q. And was your first job at Nabi as a center</p> <p>11 medical director?</p> <p>12 A. Yes. In Beloit, Wisconsin.</p> <p>13 Q. And you said now that your title is</p> <p>14 divisional medical director. And originally that</p> <p>15 was at ZLB. And now that's at CSL.</p> <p>16 Is that correct?</p> <p>17 A. Yes.</p> <p>18 Q. How many divisional medical directors does</p> <p>19 CSL have in the U.S.?</p> <p>20 A. We have two divisional medical directors.</p> <p>21 Q. And how is -- the responsibilities of</p> <p>22 those two directors divided between them?</p> <p>23 A. We try to divide the centers approximately</p> <p>24 in half. CSL currently has a little over 160</p> <p>25 centers. I oversee approximately 80 and</p>
<p style="text-align: right;">Page 11</p> <p>1 2005.</p> <p>2 Q. Let me ask just a few questions about what</p> <p>3 you told me.</p> <p>4 When you were an assistant professor, what</p> <p>5 was your area?</p> <p>6 A. Internal medicine.</p> <p>7 Q. Okay. And then when you worked at</p> <p>8 Eli Lilly, what did you do for them?</p> <p>9 A. I worked on the development of new drugs.</p> <p>10 My office was on the seventh floor of Wishard</p> <p>11 Hospital, the county hospital. And Eli Lilly had</p> <p>12 a clinical research unit there, where they tested</p> <p>13 new drugs.</p> <p>14 Q. And when you worked at Evanston Hospital,</p> <p>15 what did you do there?</p> <p>16 A. That also was as a clinical</p> <p>17 pharmacologist. There was a clinical research</p> <p>18 unit at Evanston Hospital that was affiliated</p> <p>19 with G.D. Searle, a pharmaceutical company in</p> <p>20 Skokie, Illinois.</p> <p>21 Q. And you did mention working for</p> <p>22 G.D. Searle. Was that the same time and the same</p> <p>23 work as when you were at Evanston Hospital?</p> <p>24 A. Right. The Evanston Hospital unit was</p> <p>25 only doing research on Searle's drugs at that</p>	<p style="text-align: right;">Page 13</p> <p>1 Doctor Chiu, C-H-I-U, oversees the other 80.</p> <p>2 Q. Is either of you a supervisor of the</p> <p>3 other?</p> <p>4 A. No, we are not.</p> <p>5 Q. Who is your direct supervisor?</p> <p>6 A. My direct supervisor is Wyllena</p> <p>7 Elliott-Brown, who is a divisional operations</p> <p>8 director for CSL Plasma.</p> <p>9 Q. And who is Ms. Brown's immediate</p> <p>10 supervisor?</p> <p>11 A. Her immediate supervisor would be Daniel</p> <p>12 Ferris. He is --</p> <p>13 Q. And what is Mr. Ferris's job?</p> <p>14 A. I believe his title is vice president of</p> <p>15 CSL Plasma.</p> <p>16 Q. Do you know who Mr. Ferris's supervisor</p> <p>17 is?</p> <p>18 A. Give me a second. The name slips my mind</p> <p>19 right now.</p> <p>20 Q. No problem.</p> <p>21 If you think of it later during this</p> <p>22 deposition, just let me know. Okay?</p> <p>23 A. Okay.</p> <p>24 Q. And when -- when you are dividing the</p> <p>25 centers between you and Doctor Chiu, are those</p>

John Nelson, M.D., Ph.D.

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14 to 17

<p style="text-align: right;">Page 14</p> <p>1 done geographically, in the sense that one of you</p> <p>2 does sort of the eastern half or the northern</p> <p>3 half of the country and the other the opposite?</p> <p>4 A. We try to arrange it generally</p> <p>5 geographically. It has become difficult, as we</p> <p>6 open more new centers, to keep the balance. So</p> <p>7 that -- Doctor Chiu is responsible for mainly the</p> <p>8 south and east and I'm responsible, generally,</p> <p>9 for the north and west.</p> <p>10 Doctor Chiu has been with the company</p> <p>11 approximately one year. And Doctor</p> <p>12 Haight-Biehler, who was based in Tucson, and I</p> <p>13 had a similar arrangement.</p> <p>14 Q. Are you the divisional medical director</p> <p>15 who is responsible for the CSL centers in</p> <p>16 Houston, Texas?</p> <p>17 A. Yes.</p> <p>18 Q. And is that an example of sort of</p> <p>19 a -- a -- an assignment that doesn't fit exactly</p> <p>20 with the geographical division because it's an</p> <p>21 effort to balance your workload?</p> <p>22 A. Yes.</p> <p>23 Q. Are you also the divisional medical</p> <p>24 director over the CSL center or centers in Corpus</p> <p>25 Christi, Texas?</p>	<p style="text-align: right;">Page 16</p> <p>1 Q. Are there areas in which the regulations</p> <p>2 either don't speak or are general and it is up to</p> <p>3 CSL and its company policies to fill in the --</p> <p>4 the details?</p> <p>5 A. The FDA has general regulations, as well</p> <p>6 as specific.</p> <p>7 Q. And if you are being asked a question that</p> <p>8 is subject to an FDA regulation that is only</p> <p>9 general, do you have discretion to interpret it</p> <p>10 based on the situation you're presented?</p> <p>11 A. The Medical Staff Reference -- or it's</p> <p>12 also referred to as the Medical Conditions</p> <p>13 Guide -- is our attempt to -- not codify, but to</p> <p>14 provide guidance to the individual center medical</p> <p>15 directors, as well as the medical staff</p> <p>16 associates in doing their day-to-day job.</p> <p>17 The -- occasionally I do receive questions</p> <p>18 from the medical staff associates and center</p> <p>19 medical directors regarding the interpretation of</p> <p>20 the Medical Staff Reference. And I am more aware</p> <p>21 of the FDA regulations, so I try to provide</p> <p>22 guidance for individual instances or cases so</p> <p>23 that we meet both our policies and procedures, as</p> <p>24 well as the FDA regulations.</p> <p>25 Q. I take it that it is part of your job to</p>
<p style="text-align: right;">Page 15</p> <p>1 A. I believe that Doctor Chiu is primarily</p> <p>2 responsible for Corpus Christi.</p> <p>3 Q. As the divisional medical director, could</p> <p>4 you describe for me your job duties.</p> <p>5 A. The -- my job duties include working on</p> <p>6 the Medical Staff Reference, serving as a</p> <p>7 reference or expert on medical aspects of the</p> <p>8 plasma collection business.</p> <p>9 I do a really varied number of things from</p> <p>10 day to day, but it all pertains to medical</p> <p>11 aspects of the business.</p> <p>12 Q. In your job are you given discretion in</p> <p>13 exercising your judgment about the areas that you</p> <p>14 are knowledgeable on or work on?</p> <p>15 A. I'm given discretion day to day. However,</p> <p>16 all of our policies and procedures are really</p> <p>17 limited or, I would say, developed in cooperation</p> <p>18 with the regulatory and the operations side of</p> <p>19 the business.</p> <p>20 Q. If you are being asked a question -- a</p> <p>21 medical question on which there is a regulation</p> <p>22 that specifies a certain answer, are you then</p> <p>23 constrained by that regulation?</p> <p>24 A. Yes. All of our policies, protocols and</p> <p>25 procedures serve to satisfy the FDA regulations.</p>	<p style="text-align: right;">Page 17</p> <p>1 look out for CSL's interests -- legal interests</p> <p>2 and other interests that you -- you deal with in</p> <p>3 your job, is that correct?</p> <p>4 A. My job primarily is to ensure that the</p> <p>5 donors and employees are safe and that we meet</p> <p>6 the regulations.</p> <p>7 As far as legal matters, interaction with</p> <p>8 the FDA and those sorts of things I defer to our</p> <p>9 regulatory department.</p> <p>10 Q. And if you had a question about an FDA</p> <p>11 issue, who would you contact in the regulatory</p> <p>12 department?</p> <p>13 A. The director is Jon, J-O-N, Knowles,</p> <p>14 K-N-O-W-L-E-S.</p> <p>15 Q. And is Jon Knowles a -- a medical doctor</p> <p>16 or a lawyer?</p> <p>17 A. I believe his background is science,</p> <p>18 biology.</p> <p>19 Q. Okay.</p> <p>20 Have you ever given your deposition</p> <p>21 before, Doctor Nelson?</p> <p>22 A. I recall vaguely that when I was an</p> <p>23 assistant professor at Loyola University I may</p> <p>24 have been deposed.</p> <p>25 My first experience was when I was 16</p>



<p style="text-align: right;">Page 22</p> <p>1 Indianapolis. And I frequently visit CSL Plasma</p> <p>2 centers in Indianapolis.</p> <p>3 Q. Can you give me the address -- your</p> <p>4 residence address?</p> <p>5 A. 4419 Edinburgh, E-D-I-N-B-U-R-G-H, Point,</p> <p>6 Indianapolis, Indiana 46228.</p> <p>7 Q. As part of your normal job duties, do you</p> <p>8 have occasion to go to Minneapolis?</p> <p>9 A. I visited Minneapolis maybe in March or</p> <p>10 April of this year. And the previous time was</p> <p>11 sometime in 2016.</p> <p>12 Q. Did either of those visits relate in any</p> <p>13 way to this lawsuit or the claims of Mr. Silguero</p> <p>14 or Ms. Wolfe?</p> <p>15 A. No.</p> <p>16 Q. Did either of those visits have anything</p> <p>17 to do with claims of discrimination in any way?</p> <p>18 A. No.</p> <p>19 Q. Did you review any depositions that have</p> <p>20 previously been given in this case?</p> <p>21 A. No.</p> <p>22 Q. We'll -- we'll talk about this some more,</p> <p>23 but let me ask you a broad question.</p> <p>24 You said that you had looked at the</p> <p>25 Medical Staff Reference. It was one of the</p>	<p style="text-align: right;">Page 24</p> <p>1 A. Yes, I frequently visit CSL donation</p> <p>2 centers.</p> <p>3 Q. And you are familiar with the policies and</p> <p>4 procedures that CSL has that apply to the</p> <p>5 donation process, correct?</p> <p>6 A. Yes, quite familiar.</p> <p>7 Q. As I understand it, CSL is in the business</p> <p>8 of collecting human blood plasma, is that right?</p> <p>9 A. Yes, that's the primary business of CSL</p> <p>10 Plasma.</p> <p>11 Q. And what is plasma?</p> <p>12 A. Plasma is the clear, straw-colored fluid</p> <p>13 that separates out, when you let blood sit.</p> <p>14 Q. And what is the purpose of collecting it?</p> <p>15 What does CSL use it for?</p> <p>16 A. The plasma is frozen, shipped to</p> <p>17 manufacturing centers. And there it is</p> <p>18 manufactured into pharmaceutical products.</p> <p>19 Q. And is the manufacturing done by CSL or by</p> <p>20 different companies?</p> <p>21 A. CSL plasma has manufacturing facilities in</p> <p>22 the U.S., Germany and Australia. And those</p> <p>23 manufacturing facilities produce the</p> <p>24 pharmaceutical products that are sold by CSL</p> <p>25 Behring.</p>
<p style="text-align: right;">Page 23</p> <p>1 things you looked at. Was there anything in your</p> <p>2 review of that for preparation today that you</p> <p>3 thought was erroneous or a problem?</p> <p>4 A. No.</p> <p>5 Q. And you also testified that you had looked</p> <p>6 at medical notes on the two different cases.</p> <p>7 Would those be the cases involving Mark Silguero</p> <p>8 and Amy Wolfe?</p> <p>9 A. Yes. Those were the two.</p> <p>10 Q. And, in reviewing that material, was there</p> <p>11 anything in there that you thought was in error?</p> <p>12 A. No. I did not perceive that there were</p> <p>13 errors in those medical notes.</p> <p>14 Q. I take it that you are generally familiar</p> <p>15 with the kind of plasma collection business that</p> <p>16 CSL is in.</p> <p>17 Is that right?</p> <p>18 A. Yes. I've been with the company 17 years.</p> <p>19 Q. And so you're generally familiar with what</p> <p>20 CSL does?</p> <p>21 A. Yes, I would say I'm familiar.</p> <p>22 Q. And, because of your job and work</p> <p>23 experience, you are familiar generally with what</p> <p>24 goes on in the CSL donation centers, is that</p> <p>25 correct?</p>	<p style="text-align: right;">Page 25</p> <p>1 Q. And as part of its work in collecting</p> <p>2 plasma, CSL operates plasma donation centers</p> <p>3 around the country, is that correct?</p> <p>4 A. Yes.</p> <p>5 Q. People who donate plasma at those CSL</p> <p>6 centers are paid for the donation, is that</p> <p>7 correct?</p> <p>8 A. Yes. We use paid volunteers.</p> <p>9 Q. And do you know in what form that payment</p> <p>10 is given?</p> <p>11 A. Currently that payment is given on a debit</p> <p>12 card. Formerly it was cash.</p> <p>13 Q. How much is a donor given for a plasma</p> <p>14 donation?</p> <p>15 A. Currently, the plasma donor is given</p> <p>16 approximately \$50 for the first four or five</p> <p>17 donations. After that it drops down to between</p> <p>18 20 and 40 dollars, depending on the volume of</p> <p>19 plasma donated.</p> <p>20 Q. Does CSL ever run promotions to attract</p> <p>21 donors by having extra benefits that they offer</p> <p>22 to donors?</p> <p>23 A. I really don't pay too much attention to</p> <p>24 the business side of the plasma centers.</p> <p>25 I do know that they occasionally give away</p>

<p style="text-align: right;">Page 26</p> <p>1 things such as bicycles or TVs in raffles that</p> <p>2 the donors are eligible for.</p> <p>3 Q. Is it fair to say that there is social</p> <p>4 good that comes from plasma donation?</p> <p>5 A. Yes. One of the mottos is "Good for you,</p> <p>6 good for life."</p> <p>7 Q. And the -- the "good for life" part is a</p> <p>8 recognition that plasma can be used for making</p> <p>9 medicines and therapeutic things that help</p> <p>10 people, correct?</p> <p>11 A. Correct.</p> <p>12 Q. Some -- would you agree with me that some</p> <p>13 of the people who donate plasma are motivated by</p> <p>14 altruistic reasons that we've just been talking</p> <p>15 about?</p> <p>16 MS. WILLING: Objection, lack of</p> <p>17 foundation.</p> <p>18 You can still answer.</p> <p>19 A. (Continuing) Donors donate for a variety</p> <p>20 of reasons. Some do it strictly for the money.</p> <p>21 Others are altruistic. Others know of family</p> <p>22 members who require plasma products and -- or</p> <p>23 friends -- and so their altruism is closer to</p> <p>24 home.</p> <p>25 Q. Understood.</p>	<p style="text-align: right;">Page 28</p> <p>1 regulations. And all of our policies and</p> <p>2 procedures require sign-off by the regulatory</p> <p>3 department before they are implemented or sent</p> <p>4 out to the centers.</p> <p>5 Q. And are those policies and procedures that</p> <p>6 you're referring to the ones contained in the</p> <p>7 Medical Staff Reference conditions guideline</p> <p>8 document?</p> <p>9 A. The Medical Staff Reference is one of the</p> <p>10 hundreds of policies and procedures that we have.</p> <p>11 Q. Are there any other policy or procedure</p> <p>12 documents, besides the Medical Staff Reference,</p> <p>13 that convey or translate to the staff at the</p> <p>14 centers what the FDA regulations require?</p> <p>15 A. There are -- the FDA regulations and</p> <p>16 guidelines are published on the Internet, on the</p> <p>17 FDA website. Those are available if -- to the</p> <p>18 general public if they wish to read them.</p> <p>19 The centers also learn about regulations</p> <p>20 during FDA audits and audits by other regulatory</p> <p>21 bodies.</p> <p>22 Q. What other regulatory bodies would audit a</p> <p>23 CSL donation center?</p> <p>24 A. There is the German Health Authority,</p> <p>25 which conducts audits for the European Union.</p>
<p style="text-align: right;">Page 27</p> <p>1 You've mentioned this before, but, as I</p> <p>2 understand it, CSL is required to follow certain</p> <p>3 fed -- federal regulations from the U.S. Food and</p> <p>4 Drug Administration, related to donating plasma</p> <p>5 or blood products, is that right?</p> <p>6 A. Yes. The FDA has, in the Code of Federal</p> <p>7 Regulations, specific criteria for collecting</p> <p>8 human plasma.</p> <p>9 Q. And are some of those regulations at least</p> <p>10 designed to protect the -- the plasma itself or</p> <p>11 the -- the purity of the plasma?</p> <p>12 A. The regulations protect both the purity of</p> <p>13 the plasma, as well as donor health.</p> <p>14 Q. How do the staff at CSL Plasma donation</p> <p>15 centers know what these regulations require?</p> <p>16 A. The -- as part of their training, the</p> <p>17 medical staff associates are required to read the</p> <p>18 specific subchapter relating to plasma donation.</p> <p>19 And they sign a statement that they agree to</p> <p>20 abide by the Code of Federal Regulations.</p> <p>21 Q. Are there other documents that help the</p> <p>22 medical staff associates and others at the</p> <p>23 centers to know what the regulations require?</p> <p>24 A. Really, all of our -- our policies and</p> <p>25 procedures are designed to meet the FDA</p>	<p style="text-align: right;">Page 29</p> <p>1 There is the PPTA that conducts audits. And then</p> <p>2 there are local departments of health and state</p> <p>3 departments of health that audit.</p> <p>4 Q. Other than what may be learned during an</p> <p>5 audit, is there any other reference document</p> <p>6 that -- that CSL makes available to the center</p> <p>7 staff to let them know what the FDA requirements</p> <p>8 are?</p> <p>9 A. I can't think of any, offhand.</p> <p>10 Q. Is it accurate to say that CSL is one of</p> <p>11 the world's largest collectors of human plasma?</p> <p>12 A. I believe we might be third in</p> <p>13 collections.</p> <p>14 Q. How many companies are there that do this</p> <p>15 work, let's say, in the U.S.?</p> <p>16 A. There are probably five -- what I would</p> <p>17 call major. And there are many smaller companies</p> <p>18 that might have just two or three centers.</p> <p>19 Q. CSL is a private company, correct?</p> <p>20 A. CSL Plasma is a division of CSL, which is</p> <p>21 based in Australia. And its stock is traded on</p> <p>22 the Australian stock exchange.</p> <p>23 Q. CSL is not any kind of governmental</p> <p>24 organization, is it?</p> <p>25 A. In Australia -- the company may have had a</p>

<p style="text-align: right;">Page 30</p> <p>1 close relationship with the Australian government</p> <p>2 when it was formed a hundred years ago, but now</p> <p>3 it's a publicly traded corporation.</p> <p>4 Q. And the plasma donation centers that CSL</p> <p>5 operates are open to the public, correct?</p> <p>6 A. The front door is open so that people can</p> <p>7 come into the reception area. However, the</p> <p>8 remainder of the building is not open to the</p> <p>9 public.</p> <p>10 Q. Is it fair to say that CSL is open to</p> <p>11 anyone coming in to make inquiry about donating,</p> <p>12 even if not everybody gets to donate?</p> <p>13 A. Yes, anyone can walk in the door, go to</p> <p>14 the front desk, and ask about CSL and donating</p> <p>15 plasma.</p> <p>16 Q. As part of the process of donating plasma,</p> <p>17 the CSL staff administer a donor screening, is</p> <p>18 that right?</p> <p>19 A. Prior to being able to donate, potential</p> <p>20 donors go through a screening process. It</p> <p>21 involves answering health-related questions on a</p> <p>22 kiosk, a computer data system. It includes</p> <p>23 screening of vital signs, hematocrit protein.</p> <p>24 And if those are acceptable -- even if they are</p> <p>25 not acceptable, the donor then sees a medical</p>	<p style="text-align: right;">Page 32</p> <p>1 you?</p> <p>2 A. The test for protein, if it's high, can</p> <p>3 indicate some specific diseases. It could</p> <p>4 indicate dehydration. If it's low, it may</p> <p>5 indicate malnutrition, chronic illness, liver</p> <p>6 problems or kidney problems.</p> <p>7 Q. You indicated that the vital signs are</p> <p>8 taken, in addition to checking the hematocrit and</p> <p>9 protein. Are the results of the vital signs,</p> <p>10 that hematocrit and protein shared with the donor</p> <p>11 or prospective donor?</p> <p>12 A. Yes. If the donor asks, they will be</p> <p>13 shared.</p> <p>14 Q. And is information given to the donor</p> <p>15 about -- let me start over.</p> <p>16 If the hematocrit or protein level is such</p> <p>17 that the person is not going to be allowed to</p> <p>18 donate, is that information shared to the -- to</p> <p>19 the prospective donor?</p> <p>20 A. Yes. We tell the re -- the donor the</p> <p>21 reason that they are being deferred that day.</p> <p>22 Q. And do the staff -- the CSL center explain</p> <p>23 why the hematocrit or protein level prevents</p> <p>24 their donation?</p> <p>25 A. We have donor information sheets for low</p>
<p style="text-align: right;">Page 31</p> <p>1 staff associate and they have a brief medical</p> <p>2 history and physical. And a determination is</p> <p>3 made whether they will be able to donate or not.</p> <p>4 Q. You had mentioned checking hematocrit and</p> <p>5 protein levels. Is that the same thing or are</p> <p>6 those two different tests?</p> <p>7 A. It's a -- two tests that are done on a</p> <p>8 single blood sample.</p> <p>9 Q. What does the hematocrit level show?</p> <p>10 A. The hematocrit level has to be within a</p> <p>11 FDA set range in order to donate blood or plasma.</p> <p>12 Q. And why does it have to be within that</p> <p>13 range? That is, what is the hematocrit</p> <p>14 telling -- telling you about the person?</p> <p>15 A. If the hematocrit is high, they may be</p> <p>16 dehydrated or have another medical condition.</p> <p>17 If the hematocrit is low, that would</p> <p>18 indicate anemia. And there are literally</p> <p>19 hundreds of causes of anemia.</p> <p>20 If someone's hematocrit is low, we would</p> <p>21 be concerned about taking blood out or possibly</p> <p>22 not be able to return the blood, leaving the</p> <p>23 donor with a very low hematocrit, such that it</p> <p>24 might endanger their health.</p> <p>25 Q. And what is the test for protein telling</p>	<p style="text-align: right;">Page 33</p> <p>1 hematocrit, as well as low protein.</p> <p>2 Q. Are the prospective donors given</p> <p>3 information about what they could do to change</p> <p>4 their hematocrit or protein in order to allow</p> <p>5 them to donate in the future?</p> <p>6 A. The information sheets provide suggestions</p> <p>7 or tips to the donors.</p> <p>8 The protein -- low protein one suggests</p> <p>9 things such as eating nutritious meals. We</p> <p>10 suggest to the donor that they eat before they</p> <p>11 come in and that they are well hydrated, to try</p> <p>12 to lessen the chances of the donor having an</p> <p>13 adverse event.</p> <p>14 Q. Is there a blood pressure reading that</p> <p>15 would prevent someone from donating plasma?</p> <p>16 A. Yes. The FDA has specified ranges for the</p> <p>17 systolic and diastolic blood pressures.</p> <p>18 Q. Is information given to the prospective</p> <p>19 donor, about how they might change their blood</p> <p>20 pressure in order to allow them to donate in the</p> <p>21 future?</p> <p>22 A. If the donor has a blood pressure outside</p> <p>23 the accepted range, our procedures specify that</p> <p>24 in some cases they have to be seen by the medical</p> <p>25 staff associate. The medical staff associate</p>

<p style="text-align: right;">Page 34</p> <p>1 would repeat the blood pressure reading. And,</p> <p>2 depending on what it is, may suggest that the</p> <p>3 donor needs to see their primary care physician.</p> <p>4 And if the blood pressure is quite high,</p> <p>5 we inform the donor and suggest they need to go</p> <p>6 to an emergency room or their physician as soon</p> <p>7 as possible to have that taken care of.</p> <p>8 We do, for severely high blood pressure,</p> <p>9 offer to call EMS to have the donor transported.</p> <p>10 Q. Is there a -- information sheet regarding</p> <p>11 blood pressure?</p> <p>12 A. I don't believe that we have an</p> <p>13 information sheet for high blood pressure. I</p> <p>14 don't recall at this point.</p> <p>15 Q. Am I understanding correctly, that the --</p> <p>16 that the process that the donation centers use to</p> <p>17 extract the plasma is called plasma phoresis?</p> <p>18 A. Yes, that's the term.</p> <p>19 Q. And am I understanding it correctly, that</p> <p>20 the goal of that is to remove that liquid portion</p> <p>21 of the blood and to return the nonliquid portion</p> <p>22 to the donor's body?</p> <p>23 A. Right. The plasma is what is collected.</p> <p>24 The red blood cells are returned to the donor.</p> <p>25 Q. And I'm not asking for a technical</p>	<p style="text-align: right;">Page 36</p> <p>1 measurement, fingerstick hematocrit and protein.</p> <p>2 We have medical staff associates who do the</p> <p>3 history and physical. And we have phlebotomy</p> <p>4 technicians that actually operate the machines</p> <p>5 and collect the plasma. And we have laboratory</p> <p>6 technicians that process the plasma and collect</p> <p>7 samples from it for laboratory analysis.</p> <p>8 Q. And all of those things that you just</p> <p>9 described are done on site at the donation</p> <p>10 center, is that correct?</p> <p>11 A. The -- what I described is done on</p> <p>12 location at the plasma center with the</p> <p>13 exception -- with the exception of laboratory</p> <p>14 testing. And that is done by a CSL laboratory in</p> <p>15 Knoxville, Tennessee.</p> <p>16 Q. And does that lab in Knoxville do the</p> <p>17 testing for the plasma collected at all the</p> <p>18 centers in the U.S.? Excuse me. All the CSL</p> <p>19 centers in the U.S.?</p> <p>20 A. Yes.</p> <p>21 Q. Is it fair to say that good customer</p> <p>22 service is important to CSL?</p> <p>23 A. Good customer service is quite important.</p> <p>24 Q. And are there staff awards for good</p> <p>25 customer service?</p>
<p style="text-align: right;">Page 35</p> <p>1 description of how it works, because I know I</p> <p>2 wouldn't understand it and we'd be here a long</p> <p>3 time, but I assume that this process requires</p> <p>4 fairly sophisticated machinery to accomplish?</p> <p>5 A. The machines that CSL uses are called</p> <p>6 PCS2s. And yes, they are quite complicated and</p> <p>7 sophisticated.</p> <p>8 Q. If someone wants to donate plasma, either</p> <p>9 for altruistic reasons or for the money or both,</p> <p>10 am I right that they have to go to a plasma</p> <p>11 donation center?</p> <p>12 A. There are some blood collection centers</p> <p>13 that also collect plasma, but most of the</p> <p>14 collection facilities in the U.S. are commercial</p> <p>15 concerns.</p> <p>16 Q. And CSL is one of those, correct?</p> <p>17 A. Yes.</p> <p>18 Q. And at the CSL donation centers there are,</p> <p>19 as I understand it, trained staff who screen or</p> <p>20 assess the prospective donors, is that right?</p> <p>21 A. Yes. All of our staff have to go through</p> <p>22 a training process. We have reception techs who</p> <p>23 greet the donors and enter basic information,</p> <p>24 such as demographics, into the computer system.</p> <p>25 We have screening techs that do the vital sign</p>	<p style="text-align: right;">Page 37</p> <p>1 A. I believe that at some centers they do</p> <p>2 have an employee reward system. However, I'm</p> <p>3 really not familiar with it.</p> <p>4 Q. How does the staff at the centers know</p> <p>5 that customer service is an important commitment</p> <p>6 by CSL?</p> <p>7 A. During their training I believe that all</p> <p>8 employees have training or information provided</p> <p>9 to them regarding customer service.</p> <p>10 Q. Are the plasma donation centers licensed</p> <p>11 by anyone?</p> <p>12 A. FDA license -- licenses each individual</p> <p>13 center. There is a -- initial licensing process</p> <p>14 that the center undergoes when they first open or</p> <p>15 change locations. And then every two to three</p> <p>16 years after that the FDA audits a center.</p> <p>17 Q. So if a person wants to donate plasma,</p> <p>18 they have to go to a licensed establishment for</p> <p>19 that purpose, is that correct?</p> <p>20 A. For a center to operate and ship the</p> <p>21 plasma that is collected, they have to be</p> <p>22 licensed by the FDA.</p> <p>23 Q. And the CSL Plasma donation centers in</p> <p>24 this country are licensed establishments, the way</p> <p>25 you've been describing them, is that correct?</p>



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1 Germany. And plasma from the U.S. is shipped to  
2 Germany for manufacturing. And from there it's  
3 distributed throughout the world.

4 Q. And are you saying for that reason, yes,  
5 the CSL Plasma centers in the U.S. do follow EU  
6 requirements?

7 A. Yes. The -- in order to ship the plasma  
8 into Europe, it must meet their requirements.

9 Q. I can't recall if we've used the term  
10 today or not, but my understanding is that the  
11 term "defer" means to make a decision that a  
12 person will not be allowed to donate plasma at  
13 that time.

14 Is that correct?

15 A. When we say "defer," that means the donor  
16 will not be donating that day. And deferrals can  
17 last for varying amounts of time.

18 Q. Or they may be permanent, correct?

19 A. Or they may be permanently deferred.

20 Q. So I -- I used history of cancer as an  
21 example. What about someone who has some sort of  
22 heart condition? Is there an FDA regulation on  
23 that?

24 A. No, I can't think of a specific FDA  
25 regulation. The deferrals for various heart

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1 conditions. It depends on the specific  
2 condition. They may be deferred permanently for  
3 many heart conditions.

4 Q. And am I -- am I correct, that the  
5 decision with regard to heart conditions is a  
6 matter for the company to determine?

7 A. The -- the corporate medical group has  
8 decided that we will have a Medical Staff  
9 Reference that lists many commonly seen  
10 conditions. And we have assigned deferral  
11 periods for those conditions.

12 Q. And if -- and with regard to heart  
13 conditions, that is not based on a specific  
14 regulation, but based on the company's own  
15 decision about what's appropriate, is that  
16 correct?

17 A. The FDA says that a donor must be  
18 generally healthy. And we want to ensure that  
19 the donation process will be safe for a donor.  
20 And so we have put together the Medical Staff  
21 Reference with our -- CSL's requirements.

22 Q. I just want to make sure I understand your  
23 testimony.

24 If I understand what you're saying, the  
25 FDA requirement is a healthy donor. The details

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1 of that in some instances are left to the company  
2 to determine. And with regard to heart  
3 conditions, that's one in which it's left to the  
4 company to determine.

5 Is that right?

6 A. The FDA does mandate that the donation  
7 process is safe. And they do review our adverse  
8 events when they come and audit us, such that we  
9 want to ensure that the donation process is safe  
10 for the donor. And that's why we have developed  
11 the Medical Staff Reference that provides  
12 guidelines.

13 Q. Is it possible for different plasma  
14 donation companies in the U.S. to have different  
15 standards or judgments about what kind of heart  
16 condition leads to what kind of deferral?

17 A. I believe some companies leave it more to  
18 the local center -- center medical director's  
19 discretion.

20 CSL -- because we have a large number of  
21 centers, we've decided that we will have a  
22 Medical Staff Reference. Certainly other  
23 companies -- their specific Medical Staff  
24 Reference is going to be different. We -- each  
25 company develops their own policies and

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1 procedures in isolation. We really don't share  
2 our policies and procedures with other companies.  
3 Q. You've mentioned -- we've both mentioned a  
4 few times a document called a Medical Staff  
5 Reference.

6 MR. EAST: So at this time I wanted  
7 to ask the court reporter to mark, if it isn't,  
8 and to put in front of you Exhibit 4.

9 And if you could just let me know when you  
10 have it.

11 (Brief discussion held off the record.)

12 MS. WILLING: If you want to let him  
13 know that you have it.

14 A. (Continuing) Yes, I have Exhibit 4.

15 Q. Thank you.

16 This particular version, at the upper  
17 right it shows an effective date of 27  
18 October 2014, correct?

19 A. Yes.

20 Q. And above that it says "Page 1 of 71."

21 And I'm going to be asking you to turn to  
22 some pages here in a minute. And when I do,  
23 that's the page numbering that I'll be referring  
24 to, that -- that page 1 of 71 or page whatever of  
25 71.



<p style="text-align: right;">Page 46</p> <p>1 Is that all right?</p> <p>2 A. Yes.</p> <p>3 Q. On the -- in the -- in the second</p> <p>4 paragraph of this document there is a reference</p> <p>5 to certain of the items in here being labeled</p> <p>6 "Regulatory Requirement." And those two words</p> <p>7 are in bold.</p> <p>8 Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. And then the fourth paragraph, two down</p> <p>11 from there. It says, "In those cases where</p> <p>12 regulatory requirements exist these are noted in</p> <p>13 bold type. These requirements may not be altered</p> <p>14 and deviations are not permitted."</p> <p>15 Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. And is that accurate in terms of the way</p> <p>18 CSL does its business practice and procedures?</p> <p>19 A. There are some requirements that are</p> <p>20 specific to the Code of Federal Regulations, or</p> <p>21 CFR. And the requirements must be followed to</p> <p>22 the letter.</p> <p>23 Q. Let me ask you to turn to page 18 of 71.</p> <p>24 And on the bottom half of that page, in the right</p> <p>25 column, there are a couple of boxes that say, in</p>	<p style="text-align: right;">Page 48</p> <p>1 The notation of regulatory requirement</p> <p>2 really developed out of the need for us to make</p> <p>3 the Medical Staff Reference interdigitate with</p> <p>4 other documents that we have in the center, such</p> <p>5 as in the screening booth there are lists of</p> <p>6 medications, there are geographic travel areas.</p> <p>7 And there's other information.</p> <p>8 So the Medical Staff Reference really is</p> <p>9 designed as part of -- all of our documents are</p> <p>10 to interface or interdigitate with -- with all of</p> <p>11 the other documents in the center. So that</p> <p>12 something may be listed as a regulatory</p> <p>13 requirement. It might -- something else might</p> <p>14 not be bolded, but, in fact, when you trace it</p> <p>15 back, the reason that we have it, eventually you</p> <p>16 reach a regulatory requirement.</p> <p>17 Q. And just to -- to clarify, based on your</p> <p>18 comments, I note that in that box that you were</p> <p>19 talking about, where it says, "Plasma.</p> <p>20 Acceptable if at least two donations" -- at -- at</p> <p>21 the top of that section on blood product</p> <p>22 donation, on that page, it does actually say, in</p> <p>23 bold, "Regulatory Requirement," sort of outside</p> <p>24 the if-then boxes.</p> <p>25 So can we presume that that section on</p>
<p style="text-align: right;">Page 47</p> <p>1 bold, "Regulatory Requirement." The first one</p> <p>2 says "Regulatory Requirement. If received since</p> <p>3 1980, permanent deferral."</p> <p>4 So I take it that when we see those words,</p> <p>5 "regulatory requirement," that is something from</p> <p>6 the FDA and it cannot be deviated from, correct?</p> <p>7 A. Those are regulatory requirements. And</p> <p>8 it's mandated or expected by the FDA that we</p> <p>9 would not deviate from it.</p> <p>10 Q. And, likewise, if, in the right-hand</p> <p>11 column, it doesn't say "regulatory requirement,"</p> <p>12 that reflects that the requirement is a company</p> <p>13 policy, is that correct?</p> <p>14 A. The -- these are the common medical</p> <p>15 conditions that an MSA might encounter during</p> <p>16 their evaluation of a donor. And these are</p> <p>17 expected to be adhered to for -- if you note, on</p> <p>18 page 18 of 71, in the first subheading, labeled</p> <p>19 "Plasma," "Acceptable if: At least two days</p> <p>20 between donation, no more than two donations in a</p> <p>21 seven-day period."</p> <p>22 Now, that is a very specific regulatory</p> <p>23 requirement. It's not bolded, but it is commonly</p> <p>24 understood by all the staff that it -- that that</p> <p>25 is determined by regulation.</p>	<p style="text-align: right;">Page 49</p> <p>1 blood process -- plasma product donation is based</p> <p>2 on regulatory requirements?</p> <p>3 A. Yes.</p> <p>4 Q. If you would, turn to page 28 of 71. And</p> <p>5 there their entry, for example, on depression,</p> <p>6 slash, bipolar disorder. And there is no</p> <p>7 reference, on the right-hand side of the column</p> <p>8 there, to regulatory requirement, nor is there a</p> <p>9 reference sort of at the top of that section to</p> <p>10 regulatory requirement.</p> <p>11 So can we presume that the re --</p> <p>12 restrictions described there are company policies</p> <p>13 designed to interpret the general requirement of</p> <p>14 safety and health?</p> <p>15 A. The depression/bipolar disorder is what</p> <p>16 corporate medical operations has determined that</p> <p>17 the deferral period be for these particular</p> <p>18 conditions or issues.</p> <p>19 Q. And can I assume, then, that because it</p> <p>20 doesn't mention regulatory requirement anywhere</p> <p>21 here, that this is more of a company</p> <p>22 determination, rather than an FDA determination?</p> <p>23 MS. WILLING: Objection, it</p> <p>24 mischaracterizes the evidence.</p> <p>25 You can answer.</p>

John Nelson, M.D., Ph.D.

July 12, 2017

50 to 53

<p style="text-align: right;">Page 50</p> <p>1 A. (Continuing) Corporate medical operations  2 has developed the Medical Staff Reference to  3 provide guidelines to the medical staff  4 associates.  5 The -- and in writing the Medical Staff  6 Reference, after many years and attempts, we  7 decided that this if-then format would be easiest  8 for the MSAs to understand and base their  9 decisions on.  10 Q. Not everything in this document is a  11 specific regulatory requirement, correct?  12 A. Much of the medical staff reference is --  13 has been developed over the years by the medical  14 operations group to reflect CSL's emphasis on  15 meeting the FDA regulations and making the  16 donation process safe for our donors.  17 Q. Do the FDA regulations mention the word  18 "depression"?  19 A. No. I don't think the FDA regulations  20 mention depression.  21 Q. Do they mention -- well, I'll start over.  22 If a matter is not listed on this document  23 as a regulatory requirement, the medical staff  24 associates in the centers are supposed to use  25 their judgment and can call on medical backup in</p>	<p style="text-align: right;">Page 52</p> <p>1 myself, Doctor Chiu, or two medical support  2 specialists that the MSA in the field can call to  3 ask for help in making an individual  4 determination.  5 Q. Are there times that the MSA will contact  6 the center medical director or physician about  7 an -- about an item that is listed in here,  8 seeking more information?  9 A. Yes. The medical staff associate may not  10 have dealt with a particular condition before.  11 And so they would contact the center physician or  12 center -- center medical director to help them  13 evaluate the specific individual and, you know,  14 apply the medical condition guideline.  15 Q. Are there occasions when the medical call  16 line person or medical operations person -- so  17 you or Doctor Chiu, let's say -- disagrees with  18 the center medical director or center physician?  19 A. The center medical director has not  20 written the Medical Staff Reference. It's been  21 written by medical operations. And so the center  22 medical director or the MSA's interpretation  23 might differ.  24 The medical operations is the final  25 arbiter of the interpretation. It's not uncommon</p>
<p style="text-align: right;">Page 51</p> <p>1 exercising that judgment, is that correct?  2 A. We list a lot of common medical  3 conditions. It's impossible to list everything.  4 And new drugs, treatments are developed and  5 introduced into practice every day.  6 I think we -- we capture maybe 90 percent  7 of what an MSA would encounter day to day.  8 The -- the "then" requirements for  9 deferral that we expect the MSAs to adhere to --  10 if it says, "defer for at least four months,"  11 then we expect the MSA to defer the donor for at  12 least four months.  13 They are not given the liberty of  14 decreasing the deferral period.  15 If they feel the deferral period needs to  16 be increased for a specific donor, then they can  17 discuss that with their center -- center medical  18 director. And, if they wish to, they can contact  19 medical operations and discuss the -- the  20 particular issue.  21 So these are general. We do set out  22 minimum markups that corporate medical operation  23 expect -- expects the MSA to adhere to, but, you  24 know, we can't cover everything.  25 And we do provide a call line staffed by</p>	<p style="text-align: right;">Page 53</p> <p>1 for a center director or MSA to call for  2 clarification. Sometimes that clarification can  3 be done by a medical support specialist, who is  4 an RN. Other times it is given to the divisional  5 medical director to make a determination.  6 Q. Is there anyone else who would make that  7 determination, besides the divisional medical  8 director or the -- the -- the medical support  9 specialist?  10 A. I may consult regulatory if it's a  11 question that I feel might have a regulatory  12 impact, but -- and I would defer to the  13 regulatory department if they say that it's a  14 regulatory requirement. But usually the  15 divisional medical director can make that  16 determination.  17 Very often Doctor Chiu and I will discuss  18 it. Sometimes questions point out that the  19 Medical Staff Reference needs further  20 clarification or revision. And we meet at least  21 once a year in person to revise the Medical Staff  22 Reference.  23 Q. Let me ask you to turn back to page 1 of  24 71 in this Exhibit 4. And, in particular, the  25 last section on this page, entitled "Open-Ended</p>

<p style="text-align: right;">Page 54</p> <p>1 Questions."</p> <p>2 And it gives a couple of examples of how</p> <p>3 the donor interview might be handled, is that</p> <p>4 correct?</p> <p>5 A. Yes, there are scenarios within -- within</p> <p>6 those paragraphs.</p> <p>7 Q. On the second example where the MSA is</p> <p>8 asking about epilepsy, one of the suggested</p> <p>9 questions is, "What was the cause?"</p> <p>10 Why would that be helpful to know in the</p> <p>11 donor screening process?</p> <p>12 A. The -- the reason that we ask about</p> <p>13 convulsions or epilepsy is that as part of the</p> <p>14 process, when the blood is drawn, it is mixed</p> <p>15 with sodium citrate. Sodium citrate complex is</p> <p>16 calcium, which -- calcium is needed for the blood</p> <p>17 coagulation process. If we don't add sodium</p> <p>18 citrate to the blood, it clots in the lines and</p> <p>19 in the separation bowl. And that's the end of</p> <p>20 the plasma phoresis procedure, once the blood</p> <p>21 clots.</p> <p>22 A side effect is that some of that sodium</p> <p>23 citrate is given back to the donor when the red</p> <p>24 cells are returned. And that lowers the</p> <p>25 concentration of calcium in the donor's blood.</p>	<p style="text-align: right;">Page 56</p> <p>1 A. Excuse me. I have to clear my throat.</p> <p>2 It is not uncommon that we request</p> <p>3 information from a donor's physician or pharmacy,</p> <p>4 to determine what conditions a donor might have</p> <p>5 or what medications they are taking.</p> <p>6 The -- most donors don't carry around a</p> <p>7 list of their medications. Donors might not be</p> <p>8 fully cognizant of what their medical conditions</p> <p>9 are.</p> <p>10 The -- someone may know that they have</p> <p>11 high blood pressure. The side effects, the</p> <p>12 dosage, the actual name of the medication they</p> <p>13 might not recall.</p> <p>14 The complications associated with their</p> <p>15 high blood pressure, such as cardiac hypertrophy,</p> <p>16 atherosclerosis, et cetera, they might not be</p> <p>17 aware of. They just know they have high blood</p> <p>18 pressure.</p> <p>19 Q. Are there times when the treating</p> <p>20 physician's input about whether donation would be</p> <p>21 safe is helpful in CSL making determination about</p> <p>22 allowing the donation to go forward?</p> <p>23 A. If the physician takes the time to list</p> <p>24 all of the conditions, medications, et cetera, it</p> <p>25 can be helpful.</p>
<p style="text-align: right;">Page 55</p> <p>1 That lowering of calcium can induce or cause</p> <p>2 seizures in a susceptible person. So if a donor</p> <p>3 has had convulsions, seizures, epilepsy, the</p> <p>4 plasma phoresis process may induce seizures.</p> <p>5 Q. I -- I think I follow what you're saying</p> <p>6 and understand, in light of that, why questions</p> <p>7 would be asked about those conditions.</p> <p>8 I guess what I'm wondering, though, is,</p> <p>9 why would knowing the cause of those conditions</p> <p>10 be helpful?</p> <p>11 A. Seizures or convulsions can be caused by a</p> <p>12 number of conditions. It's not uncommon for</p> <p>13 children, when they have a high fever, to have</p> <p>14 seizures. In adults, when benzodiazepines, such</p> <p>15 as Valium or Xanax, are withdrawn, a person can</p> <p>16 have seizures. During alcohol withdrawal a</p> <p>17 person can have seizures. Or a -- a donor may</p> <p>18 have epilepsy.</p> <p>19 So there are lots and lots of reasons,</p> <p>20 medical conditions, that can predispose a donor</p> <p>21 to seizures. And it's important for us to know</p> <p>22 about it.</p> <p>23 Q. Are there times when getting input from</p> <p>24 the prospective donor's own physician is</p> <p>25 requested or required?</p>	<p style="text-align: right;">Page 57</p> <p>1 Unfortunately, not all physicians are</p> <p>2 aware of what plasma phoresis is or how it's</p> <p>3 done. And they might not spend a lot of time</p> <p>4 completing the health care provider form.</p> <p>5 So yes, sometimes it's helpful. Sometimes</p> <p>6 it opens more questions than it answers.</p> <p>7 Q. Let me ask you to turn to page 3 of 71 in</p> <p>8 this Exhibit 4.</p> <p>9 And the heading to the left of the main</p> <p>10 box -- subject box on this page states,</p> <p>11 "Disabilities -- see SOP for specific guidance."</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. And at the -- at the top of the page, sort</p> <p>15 of in the center, there's a reference to this</p> <p>16 being SOP No. MA02016.</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. And does "SOP" stand for "standard</p> <p>20 operating procedure"?</p> <p>21 A. Yes.</p> <p>22 Q. So below, when it says, "see SOP for</p> <p>23 specific guidance," is it pointing out that there</p> <p>24 may be specific conditions at play that are</p> <p>25 elsewhere in this document that may give</p>

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1 that to be an SOP. Whether it's actually stated  
2 SOP or not, I don't remember.

3 Q. All right. And those documents that  
4 you've referenced -- the training document on the  
5 health assessment, the video, MA 7011 and then  
6 the associated form designation letter -- do any  
7 of those explain more fully what the assessment  
8 of gait should be looking for, what observations  
9 might lead to a deferral, or any other detail  
10 about gait?

11 A. My recollection is that in the video and  
12 perhaps in the written procedure for performing a  
13 health assessment, the gait is stated as being an  
14 indicator of impairment or other medical  
15 condition that might determine donor suitability.

16 Q. Would the fact that somebody -- excuse me.

17 Would the fact that a prospective donor  
18 uses a cane when walking automatically mean that  
19 they cannot donate?

20 A. A donor having a cane does not  
21 automatically determine whether a donor can  
22 donate. However, it is an indication that the  
23 MSA should evaluate the donor and determine the  
24 reason a cane is being used and if there are  
25 medical conditions that might prevent a donor

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1 from donating.

2 Q. The -- let me ask you the same question  
3 about a limp. Does the fact that somebody walks  
4 with a limp always mean that they will not be  
5 allowed to donate?

6 A. No. It means that there may be a  
7 condition that needs to be investigated.

8 Q. Is there any SOP outside of the MSR that  
9 relates to the use of a cane?

10 A. I don't believe that there is. In the  
11 procedure for obtaining a donor's weight, it may  
12 say that the donor has to be able to stand on the  
13 scale unaided. And a cane could come into play  
14 there, but I don't recall it specifically  
15 mentioning a cane.

16 Q. Other than the document that you described  
17 related to gait, is there any other SOP outside  
18 of this MSR that relates to limping?

19 A. No. I believe that the -- any mention of  
20 gait or limping is in the documents that I  
21 described.

22 However, the reception staff -- screening  
23 staff would -- if they observed a donor to be  
24 limping, might alert the MSA that a donor should  
25 be evaluated by the MSA.

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1 Q. There is an entry on this MSR regarding  
2 osteoarthritis, which I want to talk to you about  
3 in a few minutes. But do you recall any other  
4 SOP that CSI has related to donors or prospective  
5 donors with osteoarthritis?

6 A. No, I don't recall others.

7 Q. Can you recall any SOP outside of this MSR  
8 document that relates to donors or prospective  
9 donors with anxiety disorders?

10 A. I don't recall any other documents listing  
11 anxiety. I believe that in the information for  
12 new donors there may be mention of -- of anxiety,  
13 but I can't recall specifically that that term is  
14 used.

15 Q. And, again, other than what is in this MSR  
16 document or other -- or other versions of it, are  
17 there any SOPs that relate to the use of a  
18 service animal?

19 A. I can't recall an SOP that mentions  
20 service animals. I think it's only in MA02016.

21 Q. There, at the bottom of this page 3 -- not  
22 at the bottom, but the last entry in the text  
23 boxes -- relates to transfer to the donor bed.  
24 And, if I understand it correctly, describes a  
25 requirement that the person wanting to donate has

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1 to be able to safely transfer to and from without  
2 assistance, is that correct?

3 A. That's the statement.

4 Q. Are you aware of any SOP outside of this  
5 document, or other editions of it, that refer to  
6 that issue, describe that issue, explain that  
7 issue, or anything else related to that?

8 A. I don't recall any other documents that  
9 mention it.

10 Q. In the -- under the column "if" on this  
11 page, the second entry is "mental or behavioral."  
12 So if a donor has a mental or behavioral  
13 condition. And then, under the "then" column it  
14 says, "Acceptable if: Able to give informed  
15 consent" and "Does not violate center standards."

16 Correct?

17 A. That is the if-then statement.

18 Q. What does, "Does not violate center  
19 standards" mean or refer to?

20 A. The -- each center has general standards,  
21 as regards donor behavior. The donors are not  
22 permitted to use foul language. If a donor that  
23 has had -- if a donor has -- potential donor has  
24 an objectionable tattoo, they might be  
25 permanently deferred from donating. If the donor



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<p style="text-align: right;">Page 66</p> <p>1 behaves in a way -- does not follow directions,  2 then they may be deferred. They may be given a  3 warning. They may be deferred temporarily or  4 they may be deferred permanently.  5 I don't believe that we have a list of  6 behaviors that would result in an automatic  7 deferral or sequence of events that have to be  8 followed.  9 The center is expected to maintain a  10 professional, calm environment. Someone who is  11 argumentative or disruptive would likely be  12 warned or deferred.  13 So there is no specific list. However, I  14 think we all agree on behavior that would be  15 unacceptable in a medical or quasi medical  16 setting.  17 Q. I notice that on this page 3 there is no  18 reference to regulatory requirements. And so,  19 just to use it as an example -- the last thing we  20 were talking about. Am I correct that there is  21 no FDA regulation regarding donor behavior?  22 A. No, there are no FDA written regulations.  23 However, when the FDA comes to audit, if  24 they observe something that they feel violates  25 general decorum, they would certainly raise that</p>	<p style="text-align: right;">Page 68</p> <p>1 A. No, there are none.  2 Q. Any regulations that relate to  3 osteoarthritis?  4 A. No.  5 Q. Any regulations that relate to anxiety  6 disorders?  7 A. I don't believe there are any regulations  8 relating to anxiety disorders.  9 Q. Any regulations relating to the use of  10 service animals?  11 A. No. I do not believe that the FDA, GHA or  12 PPTA describe the use of service animals.  13 Q. Let me ask you to turn to page 4 of 71.  14 And the top half of this page -- if I  15 understand it -- is referencing a case in which  16 input from the treating physician might be  17 appropriate and how to handle that, is that  18 correct?  19 A. This is a general statement regarding  20 health care provider letters and how to manage  21 that process.  22 Q. The bottom half of this page has a general  23 heading of "Procedures and Surgeries." And then  24 it has some if-then boxes underneath it. And  25 they actually go onto the following page, I</p>
<p style="text-align: right;">Page 67</p> <p>1 with the center manager and ask them, "Why is  2 that donor here?"  3 Q. My understanding, from looking at this  4 page, is that the entry -- and I think it's the  5 fifth box down -- on "Unsteady gait, falling or  6 dizziness" -- that is not a regulatory  7 requirement, but a CSL policy, correct?  8 A. It is a CSL policy designed to ensure the  9 safety of our donors and employees.  10 Q. Is there any regulation, either U.S. or  11 otherwise, that CSL follows that mentions  12 unsteady gait from -- unsteady gait?  13 A. No. There is no specific regulation or  14 guideline that I recall, from the FDA.  15 Q. Is there any -- I'm sorry. I'm sorry. Go  16 ahead.  17 A. No.  18 From the FDA or any of the other bodies  19 that audit -- audit centers.  20 Q. And is there any regulation, from the FDA  21 or one of those other bodies, that relates to the  22 use of a cane?  23 A. No. I do not recall any regulations.  24 Q. Any regulations by the FDA or the other  25 governing bodies that relate to limping?</p>	<p style="text-align: right;">Page 69</p> <p>1 think, page 5. So there's one entry there.  2 And, if I am reading this correctly, it  3 looks like the last entry on this page 4, about  4 "procedures using flexible scopes," is actually a  5 regulatory requirement, is that correct?  6 A. The FDA has specific guidelines regarding  7 the use of flexible scopes during medical  8 procedures. And the reason for that is, flexible  9 scopes cannot be adequately sterilized. They can  10 be disinfected. However, they can be a source of  11 transmission of hepatitis and HIV.  12 Q. Some of these entries under "Procedures  13 and Surgeries" don't reflect regulatory  14 requirement. So am I correct in understanding  15 that those are based on CSL policy?  16 A. The -- well, for an example, procedures  17 using flexible scopes. We might mention a  18 procedure and say it's a four-month deferral. It  19 may trace back to the fact that flexible scopes  20 are commonly used to -- during that procedure or  21 it may be there because we feel that four months  22 are required to recover from a given procedure.  23 Q. Under "Procedures and Surgeries," on page  24 4 and 5, there is no entry regarding future  25 surgeries, is that correct?</p>



<p style="text-align: right;">Page 70</p> <p>1 A. It is correct that in this section we 2 don't discuss future surgeries. However, it's 3 not infrequent that a regular donor will discuss, 4 prior to having surgery, how long they will be 5 deferred for.</p> <p>6 The other things is that if a donor 7 mentions they may be having surgery in the 8 future, that will be a clue to the MSA that they 9 need to spend some time investigating why it is 10 that the donor believes they are going to have 11 surgery.</p> <p>12 Q. And the reason for that is, the 13 explanation for why might reveal a condition that 14 the MSR speaks to, is that right?</p> <p>15 A. It may disclose a condition that the MSR 16 speaks to. It may disclose other medical 17 conditions. It's not unusual for donors to not 18 fully understand what their medical condition is 19 and its implications for plasma phoresis.</p> <p>20 Q. The MSAs do not routinely ask about 21 upcoming or future surgeries, correct?</p> <p>22 A. The MSAs are instructed to ask open-ended 23 questions to try to illicit information from the 24 donors.</p> <p>25 They might not ask specifically, "Do you</p>	<p style="text-align: right;">Page 72</p> <p>1 joint. A torn ligament may contribute to 2 instability. A loose body can cause the knee to 3 suddenly lock, causing a person to fall. The 4 pain may be intermittent and severe, 5 cause -- causing the donor to -- to stumble.</p> <p>6 So it is important to fully elucidate what 7 the issue is. And very often that requires a 8 health care provider note. If a person is going 9 to have surgery, obviously they've consulted a 10 surgeon. And getting the information that that 11 surgeon can provide would be important to the 12 donor's suitability determination.</p> <p>13 Q. There's nothing in the FDA or other 14 regulatory requirements that mentions future 15 surgery, is that correct?</p> <p>16 A. No, but, again, it is important, to donor 17 safety and product safety, to have a full 18 understanding of a donor's medical conditions.</p> <p>19 Q. If a person indicates that they intend to 20 have surgery on their knee because of arthritis, 21 would that result in deferral?</p> <p>22 A. It depends on what conditions are 23 associated.</p> <p>24 Q. So it wouldn't be an automatic deferral, 25 but, depending on the information, it could</p>
<p style="text-align: right;">Page 71</p> <p>1 have any surgeries planned?"</p> <p>2 However, if a donor is limping or is in 3 pain, the MSA, as part of their conversation, may 4 ask about recent surgeries or planned surgeries.</p> <p>5 Q. If the -- if planned surgery is disclosed 6 by the prospective donor, you testified that 7 that's a signal to the MSA to ask further 8 questions to find out what that's about, is that 9 correct?</p> <p>10 A. Yes. The MSAs really are trained to 11 follow up on information revealed by a donor; 12 again, asking open-ended questions and eliciting 13 further information.</p> <p>14 Q. If the MSA doing that is told what the 15 surgery relates to and that is a condition that 16 this document says does not result in a deferral, 17 would the person normally be allowed to donate, 18 assuming no other conditions that trigger 19 deferral?</p> <p>20 A. It really depends on why the surgery is 21 being contemplated. For example, if someone says 22 they need knee surgery, the surgery might be done 23 for a variety of reasons. It may be done simply 24 as pain relief. It may be done if there is a 25 torn ligament or a loose bit of cartilage in the</p>	<p style="text-align: right;">Page 73</p> <p>1 uncover something that would lead to a deferral, 2 is that right?</p> <p>3 A. If the MSA feels they require further 4 information and a health care provider note, the 5 issuance of that health care provider note 6 implies that a donor is going to be deferred 7 until that health care provider note is received 8 and reviewed by the MSA and probably by the 9 center medical director.</p> <p>10 Q. What if the donor discloses that they 11 would like to have the surgery, but that's as far 12 as they've gotten with it? What should the MSA 13 do at that point?</p> <p>14 A. Again, the MSA would investigate, question 15 the donor, review what medications the donor is 16 on. Perhaps ask for a clarification of what 17 medications the doctor -- the donor is on.</p> <p>18 It really is an individualized process. 19 Each donor is an individual with a specific 20 condition. Not all arthritis or osteoarthritis 21 is -- is the same. So it's an individual 22 assessment.</p> <p>23 Q. Let me ask you to turn to page 11 of 71 in 24 this document.</p> <p>25 And the top category on that page says</p>

<p style="text-align: right;">Page 74</p> <p>1 "Anxiety Disorders," correct?</p> <p>2 A. Yes.</p> <p>3 Q. The third "if" statement under that</p> <p>4 category says, "If it requires more than two</p> <p>5 medications daily for control of symptoms or</p> <p>6 service animal required."</p> <p>7 Is that correct?</p> <p>8 A. Yes, that's the statement.</p> <p>9 Q. And then the "then" statement says, "Defer</p> <p>10 until the need for medications or animal</p> <p>11 decrease" --</p> <p>12 A. That is --</p> <p>13 Q. -- correct?</p> <p>14 A. That is the Zen -- the "then" statement.</p> <p>15 Q. Is there anything in the FDA or regulatory</p> <p>16 requirements that mentions this "two medication"</p> <p>17 or "service animal" screen?</p> <p>18 A. This is a CSL medical operations</p> <p>19 requirement or guideline.</p> <p>20 Q. What is the basis for the CSL guideline</p> <p>21 that an anxiety disorder requiring the use of a</p> <p>22 service animal results in deferral?</p> <p>23 A. The use of multiple medications or the</p> <p>24 need for service animal indicates the severity of</p> <p>25 the anxiety. And so that is the -- the "then"</p>	<p style="text-align: right;">Page 76</p> <p>1 A. Use of more than two medications would</p> <p>2 indicate that the level of anxiety is fairly</p> <p>3 severe. And so we would require that the donor</p> <p>4 be on fewer medications.</p> <p>5 Q. Would you agree with me that someone who</p> <p>6 uses more than two medications to control the</p> <p>7 symptoms of the anxiety disorder may have good</p> <p>8 results with them and may, in effect -- and may,</p> <p>9 in fact, control those symptoms with those meds?</p> <p>10 A. The donor may have good control of their</p> <p>11 symptoms.</p> <p>12 Another issue comes into play. And that</p> <p>13 is removal of the medication during the plasma</p> <p>14 phoresis procedure. A lot of medications are</p> <p>15 bound to the plasma proteins. And removal of</p> <p>16 those medications certainly might make titration</p> <p>17 of those medicines more difficult for the donor</p> <p>18 or their physician.</p> <p>19 Q. And does that difficulty depend on the</p> <p>20 kind of medication?</p> <p>21 A. It would depend on the kind of medication.</p> <p>22 It would depend on, really, multiple factors.</p> <p>23 For example, lithium -- we prohibit donors</p> <p>24 on lithium from donating. And the reason being</p> <p>25 is that the margin between a therapeutic dose and</p>
<p style="text-align: right;">Page 75</p> <p>1 statement.</p> <p>2 Q. Is this viewed as a safety issue by CSL?</p> <p>3 A. It is a safety issue. It is also a plasma</p> <p>4 center decorum issue.</p> <p>5 Q. How is it a decorum issue?</p> <p>6 A. The plasma center typically has 30 to 60</p> <p>7 beds. And the accompanying machines that are</p> <p>8 quite close together -- when a donor is having</p> <p>9 problems with their donation, it impacts the</p> <p>10 technician who is performing the procedure and it</p> <p>11 impacts other donors around the donor that's</p> <p>12 having an issue.</p> <p>13 Q. And how does the use of a service animal</p> <p>14 impact problems with the donation, or reflect</p> <p>15 problems?</p> <p>16 A. The presence of a service animal really is</p> <p>17 not an issue. At many of our centers we have</p> <p>18 visually impaired donors who will always have</p> <p>19 their service animal with them. So the presence</p> <p>20 of the service animal is usually not an issue.</p> <p>21 It's a question of the donor's medical</p> <p>22 suitability for donation.</p> <p>23 Q. And what is it about using more than two</p> <p>24 medications, for example, that tells you about</p> <p>25 their suitability for donation?</p>	<p style="text-align: right;">Page 77</p> <p>1 a toxic dose is very thin. And we simply don't</p> <p>2 want to be disturbing those donor's medication</p> <p>3 regimen. And it's for the safety of the donor.</p> <p>4 Q. In a case involving -- or start over.</p> <p>5 In a situation involving a prospective</p> <p>6 donor with an anxiety disorder taking more than</p> <p>7 two meds, would a letter from the donor's treater</p> <p>8 indicating approval with the donation affect</p> <p>9 CSL's judgment on whether to defer that person?</p> <p>10 A. The health care provider letter would</p> <p>11 provide more information, but really the decision</p> <p>12 as to whether to accept the donor is not made by</p> <p>13 the donor's health care provider. That decision</p> <p>14 is made by the MSA, the CMD and medical</p> <p>15 operations.</p> <p>16 Q. If the concern with medications is that it</p> <p>17 may affect titration and dosage, wouldn't that be</p> <p>18 something that the treating physician might be in</p> <p>19 a better position to answer than the CSL staff?</p> <p>20 A. The -- again, the treating physician may</p> <p>21 have an opinion. However, the decision to accept</p> <p>22 the donor is -- it's our decision.</p> <p>23 Q. Is there any flexibility in that decision?</p> <p>24 In other words, might there be times when someone</p> <p>25 has an anxiety disorder for which they take more</p>

<p style="text-align: right;">Page 78</p> <p>1 than two meds and CSL decides they are okay to 2 donate?</p> <p>3 A. We would really have to look at it on a 4 case-by-case basis.</p> <p>5 When we get the health care provider note 6 back, we may find that the donor is on other 7 medications or the use of a medication is for 8 another indication than what the donor believes 9 that it is for.</p> <p>10 So I would say that if they are on more 11 than two medications for anxiety, we would stick 12 with the Medical Staff Reference guideline. But 13 we would have to see what the health care 14 provider note is, what else is going on, before 15 we make a final decision.</p> <p>16 Q. And with regard to an anxiety disorder 17 that requires the use of a service animal, would 18 you agree that there are times when the use of a 19 service animal is effective in reducing the 20 symptoms of the anxiety disorder?</p> <p>21 A. I believe that people use service animals 22 because it does provide them relief.</p> <p>23 Q. Does the effectiveness of the service -- 24 use of a service animal impact CSL's decision on 25 whether that person can donate?</p>	<p style="text-align: right;">Page 80</p> <p>1 animals.</p> <p>2 Q. Did you ever have a patient with an 3 anxiety disorder who did get benefit from the use 4 of a service animal?</p> <p>5 A. Certainly many of the veterans ascribe the 6 use of a service animal as being beneficial.</p> <p>7 Q. Do you have reason to doubt their 8 description?</p> <p>9 A. It's not that I doubt their opinion. It's 10 that I have no way of objectively quantifying the 11 benefit that they receive.</p> <p>12 Q. Did you ever have a patient whose 13 functioning in the world improved because of the 14 use of a service animal? Say, for example, was 15 able to go out more places or be less fearful 16 among -- among other people?</p> <p>17 A. You know, I don't recall. And I've really 18 never studied how many people respond, what the 19 frequency of their anxiety or panic attacks are.</p> <p>20 Perhaps there's information in the 21 literature. I'm not aware of it.</p> <p>22 Q. Did you ever suggest to a patient with an 23 anxiety disorder that they consider the use of a 24 service animal?</p> <p>25 A. I can't recall an instance where I have</p>
<p style="text-align: right;">Page 79</p> <p>1 A. The need for a service animal suggests 2 that the anxiety is severe. And the -- I don't 3 think that we can quantify the level of benefit 4 that the donor -- potential donor receives. I 5 think that use of a service animal, the need for 6 a service animal, really, indicates, to me, as a 7 medical professional, that the level of anxiety 8 is severe.</p> <p>9 Q. And what do you base your judgment on, 10 that the use of a service animal for an anxiety 11 disorder indicates that it's severe?</p> <p>12 A. The -- my medical experience of the past 13 30 years -- 30-plus years indicates to me that 14 the need for a service animal classifies the 15 anxiety as being severe.</p> <p>16 The -- in terms of quantifying it, I 17 really have no way to objectively measure that.</p> <p>18 Q. What experience have you had, in the last 19 30 years, that informs your opinion about anxiety 20 disorders and the use of a service animal?</p> <p>21 A. My practice of medicine was general 22 internal medicine. And anxiety -- the treatment 23 of anxiety -- my 10 or 11 years at the VA, where 24 anxiety and PTSD are very common conditions, 25 informs my opinion regarding anxiety and service</p>	<p style="text-align: right;">Page 81</p> <p>1 suggested de novo that someone get a dog.</p> <p>2 The -- I have suggested to people that 3 they need to take a vacation, they need to go to 4 the beach and, you know, enjoy life.</p> <p>5 But in terms of specifically suggesting to 6 a patient without them asking about the benefit 7 of a service animal? No, I don't think I've ever 8 encountered that situation.</p> <p>9 Q. Did you have medical colleagues at the VA 10 or elsewhere who suggested the use of a service 11 animal for an individual with an anxiety 12 disorder?</p> <p>13 A. I really don't know.</p> <p>14 I know there are veterans organizations 15 that train animals and provide animals to vets.</p> <p>16 As far as a medical professional 17 suggesting a -- the use of a service animal, I 18 really have no information on that.</p> <p>19 Q. Did you ever have a patient who asked you 20 directly about the possibility of using a service 21 animal to help with an anxiety disorder?</p> <p>22 A. No. Again, the situations I recall -- the 23 donors -- I'm sorry -- I'm sorry -- rather, the 24 patients took it upon themselves to investigate 25 obtaining a service animal. So it's something</p>

<p style="text-align: right;">Page 82</p> <p>1 that is well known in the veteran community. And</p> <p>2 there are organizations that make that their</p> <p>3 mission. But in terms of patients seeking</p> <p>4 specific medical guidance, no, I've not had that</p> <p>5 experience.</p> <p>6 Q. Did you ever counsel a patient not to use</p> <p>7 a service animal for an anxiety disorder?</p> <p>8 A. No, I don't recall ever counseling them</p> <p>9 not to use their service animal.</p> <p>10 Q. Are you aware of any studies that describe</p> <p>11 the actual risks of someone with an anxiety</p> <p>12 disorder for which they use a service animal?</p> <p>13 A. I don't think I understand the question.</p> <p>14 Q. Are you aware of any studies regarding</p> <p>15 the -- the actual risk of having -- let me start</p> <p>16 over.</p> <p>17 If I understood your testimony earlier,</p> <p>18 you said that, in your view, someone with an</p> <p>19 anxiety disorder that requires the use of a</p> <p>20 service animal has a serious anxiety disorder.</p> <p>21 Is that what you said?</p> <p>22 A. The -- I would say qualitatively that the</p> <p>23 person has severe anxiety.</p> <p>24 As far as quantitating that, I really</p> <p>25 don't know of any studies on how to quantitate</p>	<p style="text-align: right;">Page 84</p> <p>1 different.</p> <p>2 My question is, in assessing whether the</p> <p>3 person will be allowed to donate, does the fact</p> <p>4 that the dog is well-trained and well-behaved</p> <p>5 weigh in favor of allowing -- allowing the</p> <p>6 donation?</p> <p>7 A. We assess the donor and it's a medical</p> <p>8 assessment. The requirement for a service animal</p> <p>9 indicates to me that the anxiety is of a severe</p> <p>10 nature. And so really we never get to the</p> <p>11 question of whether the service animal is</p> <p>12 well-trained or well-behaved.</p> <p>13 I would simply say that, in my experience</p> <p>14 with service animals, I have generally enjoyed</p> <p>15 having them around, because I find them to be</p> <p>16 some of the best-trained and -behaved dogs there</p> <p>17 are.</p> <p>18 Q. You said when you're assessing the donor.</p> <p>19 Is that -- with regard to anxiety disorders and</p> <p>20 the use of a service animal.</p> <p>21 Is that an individualized assessment that</p> <p>22 is done?</p> <p>23 A. All of our health assessments are</p> <p>24 individualized.</p> <p>25 Q. In making a decision about whether to</p>
<p style="text-align: right;">Page 83</p> <p>1 that.</p> <p>2 Q. Do you know of any studies that describe</p> <p>3 the risk of incidents that would be inappropriate</p> <p>4 in the plasma donation situation in terms of</p> <p>5 decorum for someone with an anxiety disorder that</p> <p>6 uses a service animal?</p> <p>7 A. I have no information regarding the</p> <p>8 incidence of panic attacks or anxiety while in</p> <p>9 the plasma center.</p> <p>10 What I do know is that donors with visual</p> <p>11 disability -- I find their service animals to be</p> <p>12 very well-trained. They present really no</p> <p>13 problems to the donor or staff.</p> <p>14 And my experience with service animals, I</p> <p>15 would say, has generally been very good.</p> <p>16 Q. In assessing whether an individual who</p> <p>17 uses a service animal as a result of an anxiety</p> <p>18 disorder can donate, would it make a difference</p> <p>19 to you if the dog were a -- well-trained and</p> <p>20 well-behaved?</p> <p>21 A. If an animal is present in the plasma</p> <p>22 center, certainly the animal has to be</p> <p>23 well-trained and behaved. I don't think there's</p> <p>24 any question about that.</p> <p>25 Q. Right. But my question is a little</p>	<p style="text-align: right;">Page 85</p> <p>1 allow a donation by someone with an anxiety</p> <p>2 disorder using a service animal, would it make a</p> <p>3 difference if the person presented as calm?</p> <p>4 A. I am confused. Can you restate the</p> <p>5 question?</p> <p>6 Q. Well, my understanding is that you are</p> <p>7 assessing a person with an anxiety disorder to</p> <p>8 see if they are appropriate to donate. And in</p> <p>9 this example the person uses a service animal.</p> <p>10 And what I'm wondering is, does the fact</p> <p>11 that the person appears to CSL staff as calm</p> <p>12 weigh in favor of allowing the donation?</p> <p>13 A. The -- what I would say is that we are</p> <p>14 performing the health assessment one time a year</p> <p>15 if the donor is a regular donor. So it is a</p> <p>16 snapshot.</p> <p>17 The -- a donor may be calm one day and be</p> <p>18 having severe behavioral issues the next.</p> <p>19 So I think that we make our best efforts</p> <p>20 to see if a donor is acceptable. Certainly CSL</p> <p>21 is in the business of collecting plasma. We want</p> <p>22 to have as many donors as possible.</p> <p>23 But, in assessing the donors, we want</p> <p>24 donors that are going to be happy and healthy and</p> <p>25 donate the most plasma they can and derive the</p>



<p style="text-align: right;">Page 86</p> <p>1 most financial benefit that they can.</p> <p>2 Q. So, to use your example, if, on the day in</p> <p>3 question, someone comes in with a service animal,</p> <p>4 discloses they have an anxiety disorder, but the</p> <p>5 dog is well-behaved and they are well-behaved and</p> <p>6 calm, might they be allowed to donate?</p> <p>7 A. The guideline that we have is that if the</p> <p>8 donor needs a service animal for anxiety, that</p> <p>9 indicates severe anxiety. And they are deferred</p> <p>10 until they no longer need the service animal.</p> <p>11 That may occur --</p> <p>12 Q. Is there any -- I'm sorry. Go ahead.</p> <p>13 A. That may occur with time, with future</p> <p>14 counseling. Whatever.</p> <p>15 But when a donor requires a service</p> <p>16 animal, we have a -- define that as being severe</p> <p>17 anxiety. And the guidelines are as written.</p> <p>18 Q. Is there any flexibility in this</p> <p>19 particular guideline, such that there are</p> <p>20 circumstances in which someone with an anxiety</p> <p>21 disorder requiring the use of a service animal</p> <p>22 will be allowed to donate?</p> <p>23 A. Again, I have -- I can qualitatively say</p> <p>24 that, you know, this person has severe anxiety.</p> <p>25 I really cannot objectively quantify. And so I</p>	<p style="text-align: right;">Page 88</p> <p>1 No. I would say that they need to be on</p> <p>2 two or fewer medications and calm before they are</p> <p>3 permitted to donate.</p> <p>4 Q. And that's true even if the five</p> <p>5 medications actually work in managing their</p> <p>6 symptoms, because you're thinking about their</p> <p>7 condition without the medications and how severe</p> <p>8 it must be to require five meds, is that right?</p> <p>9 A. The -- it's an assessment of their degree</p> <p>10 of anxiety. It's also assessing potential for</p> <p>11 adverse events.</p> <p>12 The use of multiple medications -- we have</p> <p>13 limits in hypertension. Yes, someone's blood</p> <p>14 pressure may be well controlled, but if they are</p> <p>15 on five medications, I think that presents an</p> <p>16 issue of safety. And I'm not going to permit the</p> <p>17 donor to donate.</p> <p>18 Q. Are you aware of any studies regarding the</p> <p>19 potential for adverse events in someone with an</p> <p>20 anxiety disorder requiring the use of a service</p> <p>21 animal?</p> <p>22 A. I don't believe there is any information</p> <p>23 in the literature.</p> <p>24 Q. Do you have any observations yourself</p> <p>25 about the potential for adverse events with</p>
<p style="text-align: right;">Page 87</p> <p>1 would say that we will stick with this guideline.</p> <p>2 And when MSAs call me, the answer I always</p> <p>3 give is that use of the service animal indicates</p> <p>4 severe anxiety. And we do not accept the donor</p> <p>5 until they no longer need the service animal.</p> <p>6 Q. When you say that the use of a service</p> <p>7 animal indicates severe anxiety, would you agree</p> <p>8 with me that it's possible that that was severe</p> <p>9 anxiety prior to the use of a service animal and</p> <p>10 there -- may not have severe anxiety with the use</p> <p>11 of a service animal?</p> <p>12 A. The person may experience relief of their</p> <p>13 symptoms.</p> <p>14 The -- however, to objectively quantify</p> <p>15 that, I find that impossible. So, you know, a</p> <p>16 donor may tell us a lot of things, but I really</p> <p>17 have no way to objectively assess it.</p> <p>18 Q. Except that the MSA who is meeting with</p> <p>19 the donor has a way to objectively assess the</p> <p>20 presentation of the person that day, correct?</p> <p>21 A. I would draw the correlation with more</p> <p>22 than two medications. The -- I -- if someone</p> <p>23 comes in with five medications and would I say</p> <p>24 "Oh, they look calm today, go ahead and let them</p> <p>25 donate?"</p>	<p style="text-align: right;">Page 89</p> <p>1 someone who uses a service animal for anxiety</p> <p>2 disorders?</p> <p>3 A. Well, we don't permit donors with service</p> <p>4 animals to donate, so we're not going to have</p> <p>5 that information.</p> <p>6 Q. How about before you worked at CSL, at the</p> <p>7 VA or elsewhere, did you make any observations</p> <p>8 about the potential for adverse events in</p> <p>9 patients with anxiety disorder using service</p> <p>10 animals?</p> <p>11 A. Certainly people like to have their</p> <p>12 service animals with them.</p> <p>13 In terms of adverse events in a hospital</p> <p>14 or clinic, between donors that have their service</p> <p>15 animal with them and donors that don't, I don't</p> <p>16 think there's any information. I really have no</p> <p>17 personal information that would allow me to make</p> <p>18 a definitive statement.</p> <p>19 Q. Who was it that wrote this particular</p> <p>20 limitation on more than two meds or use of the</p> <p>21 service animal?</p> <p>22 A. The Medical Staff Reference was first put</p> <p>23 together in 2005 or 2006, in that date range --</p> <p>24 maybe a little bit later, 2007 -- by</p> <p>25 Doctor Haight-Biehler, who was a divisional</p>



John Nelson, M.D., Ph.D.

July 12, 2017

90 to 93

<p style="text-align: right;">Page 90</p> <p>1 medical director; myself; and at the time I think  2 it may have been Jan Hamilton, the corporate  3 medical director. Certainly, for later  4 revisions, it was Doctor Toby Simon. And since  5 that time we have made several revisions to this  6 document, over the years.  7 We meet yearly to review the document and  8 make changes. The -- I don't recall whether it  9 was my suggestion that we add this or  10 Doctor Biehler's, but it was one of us.  11 Q. And who is Toby Simon?  12 A. Toby Simon was the corporate medical  13 director for CSL Plasma for about the past --  14 well, about five years ago -- four or five years  15 ago. He moved to CSL Behring. So he's not the  16 CSL Plasma corporate medical director at this  17 point, but he does interface with us because of  18 his experience and knowledge.  19 Q. And remind me. What is the relationship  20 between your position and the corporate medical  21 director?  22 A. Previously, when I was first hired, I  23 reported to the corporate medical director, who  24 was Jan Hamilton. And then Jan left and  25 Doctor Simon joined as the corporate medical</p>	<p style="text-align: right;">Page 92</p> <p>1 uses a service animal to donate?  2 A. No, I don't believe anyone has that  3 information. Medical operations is responsible  4 for monitoring adverse event data company-wide.  5 And I have -- I don't believe I have the  6 information that would permit me to study that  7 question.  8 MR. EAST: Stephanie, let me go off  9 the record and ask you about taking a break, if  10 we could?  11 MS. WILLING: Yeah, let's do it.  12 (Recess from 12:24 p.m. to 1:16 p.m.)  13 MR. EAST: Okay. Let's go back on  14 the record.  15 Q. (By Mr. East, continuing) Doctor Nelson,  16 we're back on the record after a lunch break.  17 And I was asking you about some of the entries  18 regarding anxiety disorder on page 11 of  19 the -- of the MSR that's been labeled 4 here.  20 Was -- were these policies regarding  21 anxiety disorder drafted in response to  22 something?  23 A. CSL -- at the time it was Nabi -- was  24 maybe 12 locations, 12 centers. Then it merged  25 with Aventis to become ZLB, which bumped the</p>
<p style="text-align: right;">Page 91</p> <p>1 director.  2 Since Doctor Simon left we have -- I have  3 not reported to the corporate medical director,  4 because there is not a corporate medical  5 director.  6 My assessments, my day-to-day HR needs are  7 handled by Ms. Elliott-Brown, who is the  8 divisional operations director.  9 For a time I did report to Michelle Myers,  10 who was the corporate quality director.  11 And I have reported at times to Scott  12 Newkirk, who was -- who is a divisional  13 operations director.  14 But for the last year and a half I've been  15 reporting to Ms. Elliott-Brown.  16 Q. I had asked you earlier about your  17 awareness of studies of risk or observations  18 you've made about the risk of adverse events.  19 Let me just ask the same question, but  20 broaden it, so that I'm not just asking about  21 your own personal knowledge.  22 But are you aware of any information that  23 CSL has to indicate the potential -- the --  24 the -- yeah, the potential for adverse events in  25 allowing someone with an anxiety disorder who</p>	<p style="text-align: right;">Page 93</p> <p>1 number up to about 60 centers. And there were  2 three physicians at the time that could answer  3 questions and be on call.  4 CSL has expanded greatly. We're over 160  5 centers now. Even back then, to keep up with  6 phone calls, we decided that we would have a  7 Medical Staff Reference or conditions guide for  8 MSAs to work from. And so we put together the  9 conditions guideline. I believe we have always  10 had a -- a -- item about anxiety. And the  11 if-then statements have evolved over the years.  12 And that evolution has been in response to  13 questions from the MSAs and the center, as well  14 as our experience in what sort of questions we  15 were most frequently called about, areas where  16 clarification was needed.  17 So the Medical Staff Reference has always  18 been 60 or 70 pages, but over the years the  19 format and -- has evolved and we have refined our  20 if-then statements.  21 Q. Do you recall when the if-then statement  22 was changed to add -- or -- start over.  23 Do you recall when the if-then statement  24 first referenced the use of a service animal for  25 anxiety disorder?</p>

<p style="text-align: right;">Page 94</p> <p>1 A. I really don't recall that, which revision</p> <p>2 it was.</p> <p>3 Q. Would that have been near the beginning of</p> <p>4 the MSR and its evolution?</p> <p>5 A. It -- it has been -- service animal has</p> <p>6 been in the MSR for a very long time. At one</p> <p>7 point it was in -- on page 1 or 2, regarding</p> <p>8 disabilities. And later on it was moved to the</p> <p>9 anxiety disorder subheading.</p> <p>10 Q. And was the addition of the service animal</p> <p>11 piece regarding anxiety disorder the result of</p> <p>12 some incident or incidents that had occurred at</p> <p>13 donation centers?</p> <p>14 A. I -- I really don't recall. It's been</p> <p>15 probably eight or nine years ago. And I don't</p> <p>16 recall if it was in response to questions from</p> <p>17 center medical staff or whether it was in</p> <p>18 response to events that occurred. So I can't --</p> <p>19 I can't provide you with an answer there.</p> <p>20 Q. Do you know of anybody who would know more</p> <p>21 about the response to that question?</p> <p>22 A. Doctor Haight-Biehler, who was based in</p> <p>23 Tucson, but she left the company a couple of</p> <p>24 years ago.</p> <p>25 Q. Anybody else?</p>	<p style="text-align: right;">Page 96</p> <p>1 handled?</p> <p>2 A. I have no information about that.</p> <p>3 Q. Who would know that?</p> <p>4 A. I don't believe anyone would have that</p> <p>5 information available. The -- certainly the</p> <p>6 regulatory department keeps records of when</p> <p>7 audits were done. Over the last 17 years that</p> <p>8 I've been with the company, we're talking about</p> <p>9 hundreds, if not over a thousand audits.</p> <p>10 Q. In your clinical practice before CSL, what</p> <p>11 kinds of things would you look at to determine if</p> <p>12 a patient's anxiety disorder was controlled or</p> <p>13 not?</p> <p>14 A. Anxiety would be something that would be</p> <p>15 self-reported by the donor or by a patient. So</p> <p>16 it would be something that the patient would</p> <p>17 bring to my attention.</p> <p>18 In terms of assessing, you know, whether</p> <p>19 the donor requires medications or they need their</p> <p>20 medication regimen adjusted, that would be an</p> <p>21 interaction that would be initiated by the</p> <p>22 patient. They would say, you know, "Last week I</p> <p>23 had two panic attacks. I don't feel that things</p> <p>24 are under control."</p> <p>25 Q. Does the severity of an untreated anxiety</p>
<p style="text-align: right;">Page 95</p> <p>1 A. No.</p> <p>2 Jan Hamilton --</p> <p>3 Q. Can you think of --</p> <p>4 A. Jan Hamilton --</p> <p>5 Q. I'm sorry?</p> <p>6 A. Yeah. Jan Hamilton --</p> <p>7 Q. Uh-huh.</p> <p>8 A. -- was --</p> <p>9 Q. Yes?</p> <p>10 A. -- our corporate medical director at the</p> <p>11 time we were -- first put the Medical Staff</p> <p>12 Reference together. But she is deceased now.</p> <p>13 Q. Can you think of any documentation that</p> <p>14 would help to answer the question of why this was</p> <p>15 added?</p> <p>16 A. No. There really is no documentation.</p> <p>17 When we revise the Medical Staff Reference, that</p> <p>18 is done as a group, sitting around a conference</p> <p>19 table. And one person has the current Medical</p> <p>20 Staff Reference pulled up on their computer. And</p> <p>21 it's a realtime revision that goes on. So there</p> <p>22 is no other documentation of the revisions.</p> <p>23 Q. Has CSL ever received input from an FDA</p> <p>24 audit about incidents related to anxiety</p> <p>25 disorders and the way they might have been</p>	<p style="text-align: right;">Page 97</p> <p>1 disorder tell you anything about the likelihood</p> <p>2 of there being problems on the donor floor if</p> <p>3 they were being treated?</p> <p>4 A. I really don't know how to answer that</p> <p>5 question. I -- a donor may be having anxiety.</p> <p>6 If it's severe anxiety, they would not be</p> <p>7 permitted to donate. They may come back later,</p> <p>8 on medication, and be improved and no longer</p> <p>9 having anxiety symptoms or panic attacks. And at</p> <p>10 that time they may be acceptable. But</p> <p>11 determining how medication influences risk for</p> <p>12 DAE, an adverse event, I don't know that I have</p> <p>13 any --</p> <p>14 Q. What did --</p> <p>15 A. -- that I have any information on that.</p> <p>16 Q. I'm sorry. Go ahead. You don't know that</p> <p>17 you have any ...?</p> <p>18 A. Information.</p> <p>19 Q. What does "DAE" stand for?</p> <p>20 A. Donor adverse event.</p> <p>21 Q. And in the context of anxiety, can you</p> <p>22 give me some examples of DAEs --</p> <p>23 A. Most --</p> <p>24 Q. -- that -- that you've seen or that staff</p> <p>25 have seen?</p>

<p style="text-align: right;">Page 98</p> <p>1 A. In answering this, I have to describe our</p> <p>2 adverse event monitoring and management system.</p> <p>3 There are nonreportable adverse events,</p> <p>4 where something occurs and it's managed without</p> <p>5 the intervention of a medical staff associate.</p> <p>6 The phlebotomist is able to do something, change</p> <p>7 something that relieves the donor's symptoms.</p> <p>8 There are also reportable adverse events.</p> <p>9 And those are codified by the PPTA, which</p> <p>10 monitors a company's adverse event rate.</p> <p>11 There are specific criteria that</p> <p>12 determine -- determine whether an adverse event</p> <p>13 is reportable. If it falls into that reportable</p> <p>14 category, then we complete a form describing</p> <p>15 symptoms, signs, treatment, response. The MSAs</p> <p>16 manage most adverse events. The -- part of the</p> <p>17 form includes a call back to the donor the next</p> <p>18 day, to make sure they are okay.</p> <p>19 And then the third part of the form is a</p> <p>20 review by the center medical director, to</p> <p>21 determine whether the donor is suitable to</p> <p>22 continue to donate.</p> <p>23 The -- I do not believe that we break it</p> <p>24 out by previous medical diagnoses or we don't</p> <p>25 have information about previous reported anxiety</p>	<p style="text-align: right;">Page 100</p> <p>1 in our informed consent -- in both the written</p> <p>2 and the video information about informed consent.</p> <p>3 Citrate that's mixed with the blood to</p> <p>4 prevent coagulation works by lowering calcium. A</p> <p>5 small amount of that citrate is reinfused into</p> <p>6 the donor, along with the red cells. That can</p> <p>7 cause anxiety. As we talked about earlier,</p> <p>8 seizures, muscle cramps, tingling of the face and</p> <p>9 lips, a feeling of not being able to breathe or</p> <p>10 catch their breath. And it can be quite</p> <p>11 fear-inducing. It can be -- most of those are --</p> <p>12 are managed in the center, but we have had donors</p> <p>13 requiring transport due to those symptoms.</p> <p>14 So the -- it can be quite ang -- cause a</p> <p>15 lot of anxiety and fear.</p> <p>16 The -- it also -- the citrate can cause a</p> <p>17 metallic taste in the mouth, nausea, vomiting.</p> <p>18 And I used to donate. And that was</p> <p>19 the -- one of the more disturbing parts of my</p> <p>20 donation, was the metallic taste and nausea.</p> <p>21 The -- when donors discontinue the</p> <p>22 donation early, they don't get their saline,</p> <p>23 which is given at the end of the procedure. They</p> <p>24 are definitely at increased risk for fainting and</p> <p>25 falling.</p>
<p style="text-align: right;">Page 99</p> <p>1 and the development of adverse events, so there</p> <p>2 is no data. There is no way for me to look at</p> <p>3 the donor adverse event data and break it out by</p> <p>4 people with a history of anxiety versus not.</p> <p>5 Q. Would you agree, treated -- a treated</p> <p>6 anxiety disorder -- I'm going to start over.</p> <p>7 Would you agree that someone who is</p> <p>8 getting treatment for an anxiety disorder will</p> <p>9 have a reduced likelihood of an incident that</p> <p>10 would interfere with the safety of -- of the</p> <p>11 donation process?</p> <p>12 A. The -- that is our hope.</p> <p>13 As far as giving you statistics, no, I</p> <p>14 don't have any statistics. But it would be our</p> <p>15 hope that the donor would be less likely to have</p> <p>16 an adverse event.</p> <p>17 The adverse event can be anything from the</p> <p>18 donor not being able to continue and complete the</p> <p>19 donation. We have had donors pull the needle out</p> <p>20 and run out of the center. We've had donors that</p> <p>21 have anxiety and have to stand up. You know,</p> <p>22 they are really compelled to -- to do that.</p> <p>23 Difficulty breathing.</p> <p>24 The -- one of the not uncommon adverse</p> <p>25 events is a citrate reaction, which we describe</p>	<p style="text-align: right;">Page 101</p> <p>1 The part of the reaction that we commonly</p> <p>2 see is an intense urge to go to the bathroom.</p> <p>3 And if a donor has to run to the bathroom in the</p> <p>4 middle of the procedure, that usually heralds a</p> <p>5 fall -- fainting and a fall.</p> <p>6 And the injuries that I've seen over the</p> <p>7 years -- some have been quite severe. Donors</p> <p>8 losing teeth, suffering a concussion. Falls</p> <p>9 often result in a call to EMS and the transport</p> <p>10 of the donor.</p> <p>11 So it's -- it's also -- can impact</p> <p>12 employee safety and safety of other donors.</p> <p>13 I've had instances where donors start</p> <p>14 flailing about and the needle becomes dislodged</p> <p>15 and an employee ends up with a -- a needlestick</p> <p>16 injury. Or other donors get sprayed with blood.</p> <p>17 And so it's really not something to be taken</p> <p>18 lightly.</p> <p>19 It -- donors going home happy on -- donors</p> <p>20 go home unhappy, but to protect the safety of the</p> <p>21 donors, employees, other donors, we have</p> <p>22 developed our guidelines. I think they are</p> <p>23 fairly encompassing. We cover a lot of</p> <p>24 conditions, but I feel really quite confident</p> <p>25 that -- that they are a good set of guidelines.</p>

John Nelson, M.D., Ph.D.

July 12, 2017

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1 And we will continue to use them and -- and  
2 refine them.

3 Q. Some of the adverse anxiety events that  
4 have happened at CSL donation centers have  
5 involved people with no known or diagnosed  
6 anxiety disorder, correct?

7 A. It's not uncommon, for people who have  
8 adverse events, to later on reveal that they have  
9 a medical condition or have anxiety problems or  
10 are taking medications that they did not tell us  
11 about. It -- it's always difficult to figure  
12 out.

13 If they require transport, that is often a  
14 come-to-Jesus moment, when people do reveal their  
15 medical history.

16 I am not saying that either of these  
17 donors was not completely truthful with us, but,  
18 in my experience over the years, I've seen that  
19 quite commonly.

20 Q. Are there times when there's an adverse  
21 event related to anxiety in people who do not  
22 have a diagnosis or treatment?

23 A. Yes. People do come in and realize that  
24 they are afraid of needles. It's not unheard of  
25 for a six-foot-four, 260-pound male to faint when

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1 they get their finger stuck. So, you know,  
2 it's -- we're dealing with the general population  
3 and so we see all of these things.

4 Q. I -- I apologize if I asked you this  
5 already, but is there anyone at CSL who you  
6 believe has more information than you about  
7 anxiety disorders or anxiety disorders requiring  
8 the use of a service animal?

9 A. No. I believe I have the most experience.  
10 And we have individual center medical directors  
11 that have been in the business longer than I  
12 have, but, on a corporate level, I have the most  
13 seniority.

14 Q. Is it -- is it possible that a donor who  
15 has a severity anxiety disorder could donate  
16 safe -- safely and without an issue?

17 A. I'm sure that there are donors that have  
18 responded to treatment and donate quite  
19 successfully.

20 Q. Let me ask you to look again at page 11  
21 of -- regarding anxiety disorders. And the first  
22 entry under "if." It says "severe" and  
23 "frequent" and resulting in a permanent deferral.

24 What does "severe, frequent" mean there?

25 A. It really has to be elicited in the

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1 interview with the donor.

2 Q. And how is that determined, as how is  
3 "severe" or "frequent" determined? I know you  
4 said it's listed in the interview, but what are  
5 you asking? What are you looking for?

6 A. If the donor is on a medication that's  
7 used to treat anxiety, we would ask them, "Why  
8 are you on this medication?"

9 If they respond, "It's my anxiety  
10 disorder," or PTSD, then we would delve into that  
11 further.

12 Again, trying to use open-ended questions.  
13 And let the donor tell us in their own words.

14 Q. What kinds of questions would you expect  
15 would be asked to delve into that further?

16 A. The questioning really is in response to  
17 specific things that the donor might say. We may  
18 ask if it's situational, how severe is it. We  
19 would try to get a -- a clearer picture of the  
20 donor.

21 Q. And under the last if-then statement under  
22 "Anxiety Disorders," it says, "If currently with  
23 symptoms, temporary deferral."

24 What does "symptoms" mean there?

25 A. Any symptoms of anxiety: sweating,

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1 nervousness, palpitations, the feeling of fear,  
2 wanting to get out of the center. There are  
3 really a wide variety of -- of symptoms that a  
4 person might -- might develop.

5 Q. I asked you earlier about what the safety  
6 issues implicated here are. And you were talking  
7 about decorum issues. And, if I understood you  
8 correctly, you were not talking about the decorum  
9 of the animal, but the decor -- decorum of the  
10 donor.

11 Have I understood your testimony  
12 correctly?

13 A. Yes. The -- we don't allow donors with  
14 severe anxiety to donate, so it's not a question  
15 of the animal. What we're talking about would be  
16 the environment in the center.

17 Q. Are you familiar with the diagnosis  
18 "generalized anxiety disorder"?

19 A. I have not looked -- that sounds like  
20 something from the DSM. I have not reviewed that  
21 in a couple of years.

22 Q. Would you agree with me that the DSM is  
23 sort of the authoritative handbook on mental  
24 disorders?

25 A. It describes the symptoms and things that



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1 you observe. And it categorizes those into  
2 diagnoses. Often it's a checklist type of thing.  
3 And so it's useful for psychiatrists. It's  
4 useful for billing purposes when physicians seek  
5 reimbursement for their services.

6 In terms of general utility outside of  
7 those settings, I'm not sure that that's the  
8 intended use.

9 Q. Would it be fair to say that it's written  
10 primarily for professionals?

11 A. Yes. That's -- it's written primarily for  
12 mental health professionals.

13 Q. And is it updated from time to time to  
14 correct or -- or coincide with current thinking  
15 and research?

16 A. It is updated. When it is updated, you  
17 frequently see it in the popular press. And it's  
18 not always without controversy that it is  
19 updated.

20 Q. Is it something that, for professionals,  
21 is considered authoritative?

22 A. I think that in any professional  
23 discussion, conferences, literature, it is the --  
24 it supplies the basic definitions that people  
25 use.

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1 Q. And by "people," you mean professionals?

2 A. Professionals, yes.

3 Q. Do you use it at -- in your work at CSL?

4 A. I have looked at it in the past. I really  
5 can't point to a specific instance where I said,  
6 "Let's refer to the diagnostic and statistics  
7 manual to refine our if-then formatted  
8 questions."

9 Q. In your clinical practice have you used  
10 the DSM?

11 A. Yes. In my training and -- and clinical  
12 practice I have reviewed it. The -- in terms of  
13 using it, I do not use it on -- on a day-to-day  
14 basis, but if I have a question, I -- I will look  
15 at a topic.

16 Q. Are you familiar with the diagnosis "panic  
17 disorder"?

18 A. Yes, I am familiar, but it's been a long  
19 time since I've looked at it.

20 Q. What is your understanding of what that  
21 diagnosis means for an individual?

22 A. I would really have to have a copy of the  
23 DSM in front of me to -- to discuss it.

24 Q. And what about the diagnosis of  
25 "post-traumatic stress disorder"? Are you

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1 familiar with that?

2 A. Yes.

3 Q. Do you know the symptoms or manifestations  
4 or criteria for that?

5 A. There again, I would need the DSM in front  
6 of me to -- to discuss it.

7 Q. Let me ask you to turn to page 13 of 71 in  
8 the exhibit in front of you. And the top entry  
9 there is for arthritis. And under the "if"  
10 column it says, "If ... All others, including  
11 osteoarthritis," then Acceptable if: No  
12 disqualifying medications."

13 Did I read that accurately?

14 A. Yes, that's what it says.

15 Q. And so am I understanding it correctly,  
16 that osteoarthritis, the diagnosis, is not  
17 grounds for deferral, although someone could be  
18 taking in medicine for it, that would be grounds  
19 for deferral?

20 A. They may be deferred due to medications.  
21 They may be deferred due to other symptoms. If  
22 they have difficulty getting on and off the bed,  
23 if they have difficulty standing on the scale, if  
24 they are unsteady on their feet, it -- those may  
25 also cause deferral. It's not simply in

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1 disqualifying medications.

2 Q. Also on that page there's an entry for  
3 "Asperger's Syndrome, slash, Disorder,"  
4 indicating that that is not grounds for deferral,  
5 correct?

6 A. Yes.

7 Q. And at the bottom of the page there's an  
8 entry for asthma. And on -- on the following  
9 page, page 14, it has the if-then statements.  
10 And they indicate that certain things will result  
11 in deferral and other things won't.

12 Is that a fair characterization?

13 A. Yes. We have multiple if-then statements.

14 Q. And some situations regarding asthma do  
15 not result in a deferral, correct?

16 A. Some situations do not, according to the  
17 if-then statements, but, there again, you need to  
18 look at the whole patient -- or donor. And there  
19 may be issues regarding the number of medications  
20 that are required.

21 There can also be -- if you observe the  
22 donor walking into the center or walking into the  
23 MSA office and they are huffing and puffing and  
24 short of breath, that would indicate that the  
25 asthma is severe and that the donor is going to



<p style="text-align: right;">Page 110</p> <p>1 be deferred or we're going to require a health  2 care provider note or it's not simply asthma.  3 There may be COPD, as well.  4       So yes, these are the general if-then  5 statements, but there may be other things going  6 on. You may observe other things that would  7 result in the donor's deferral or result in a  8 health care provider note being requested.  9       Q. Let me ask you to turn to page 43 of this  10 document. And on that page there is a -- a --  11 three -- for joint replacement. And the if-then  12 statements suggest that a person with joint  13 replacement is not deferred if it's been a  14 sufficient time since -- since the surgery. And  15 I believe it says eight weeks for small joints  16 and four months for large.  17       Did I characterize that correctly?  18       A. Those are the if-then statements.  19       Q. Is there anything else to add to the  20 deferral decision regarding joint replacements?  21       A. This is assuming that the surgery went  22 well, there was no problem healing. If there was  23 infection, complications, such as a deep-vein  24 thrombosis, other medications that the donor  25 might now be on.</p>	<p style="text-align: right;">Page 112</p> <p>1 older, they would probably end up with a -- a  2 cardiac evaluation preop. And those would all be  3 things that we would be interested in hearing  4 from the donor.  5       Q. There's nothing in this entry or elsewhere  6 in the MSR about upcoming or future joint  7 replacement surgery, correct?  8       A. We do not have a -- if-then statement  9 about future surgery. However, again, it would  10 be of interest to know why the person is having  11 the surgery, what other medical problems might be  12 accompanying, and the general health of the  13 person.  14       Q. Let me ask you to turn to page 53 of this  15 document, if you would.  16       And towards the bottom of the page there  17 is an entry for "Post-Traumatic Stress Disorder."  18 And it reflects that someone with PTSD is  19 acceptable to donate if the condition and  20 medications are stable, is that correct?  21       A. Yes. Also part of that statement is, "See  22 Anxiety Disorders."  23       Q. And that's the entry that we've already  24 looked at before, on page 11, is that right?  25       A. Right.</p>
<p style="text-align: right;">Page 111</p> <p>1       So this is sort of the minimum. And there  2 are other questions that need to be answered  3 before we would accept the donor.  4       Q. And how do the staff know what those  5 questions are?  6       A. The staff are paramedics, RNs and LPNs, so  7 they have experience in the medical field. They  8 have training and experience. And if they have  9 any questions, they can call their CMD or they  10 can call MedOps.  11       It -- the questions are, again,  12 open-ended. Let the donor tell their story.  13       If something doesn't seem right, call the  14 CMD, call MedOps, ask for a health care provider  15 note.  16       Q. And am I right that there is nothing in  17 the FDA or other regulations that specifically  18 references joint replacement?  19       A. No, there is nothing that addresses joint  20 replacement. However, there are requirements  21 regarding blood transfusions or cadaver cartilage  22 or those sorts of questions that might -- might  23 be involved.  24       Certainly any time someone goes under, has  25 a major surgery, if it's nonemergent, and are</p>	<p style="text-align: right;">Page 113</p> <p>1       Q. Okay. Let me ask you, if you would, to  2 look at something that either has been or will be  3 marked as Exhibit No. 6.  4       (Brief discussion held off the record.)  5       (Deposition Exhibit No. 6 marked.)  6       A. (Continuing) I have number 6.  7       Q. All right. And let me point out that at  8 the top right corner it reflects the effective  9 date of 23 May 2016. And Exhibit 4 that we were  10 looking at had an effective date of 27 October  11 2014.  12       So this is a more recent version of the  13 MSR, is that correct?  14       A. Yes.  15       Q. There may be one or two changes that I  16 wanted to ask you about. Most of this seems very  17 similar to me.  18       But if you look at page 3 of Exhibit 6, 3  19 of 73. Again, that's the disabilities section.  20 And it has similar language in some ways to what  21 we looked at before, but this one under  22 "Disabilities" says, "See CTR02121, Impaired  23 Donors for specific guidance."  24       Do you see that?  25       A. Yes.</p>

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1 came out, did it make any changes with regard to  
2 assessing the donor's gait?

3 A. There are no changes to assessing the  
4 donor's gait.

5 Q. Are there any changes that would impact a  
6 donor's use of a cane?

7 A. No.

8 Q. Are there any changes to that that relate  
9 to a donor's limp?

10 A. No.

11 Q. Any changes to the entry on  
12 osteoarthritis?

13 A. No.

14 Q. Any changes to the entry on anxiety  
15 disorders?

16 A. No.

17 Q. And any changes to the entries on service  
18 animals or assistance animals?

19 A. No.

20 Q. You -- I think when you were describing  
21 the -- the screening process that goes on at a  
22 CSL Plasma donation center, you referenced that  
23 one of the facts that they do is weigh the donor  
24 or prospective donor. And you also referenced  
25 the ability to get on the scale, et cetera.

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1 Is there an FDA regulation regarding the  
2 weight of the donor?

3 A. The donor's weight determines the volume  
4 of plasma that they can donate. I believe that a  
5 donor can be no less than 110 pounds to donate.

6 The -- I don't think the FDA proscribes an  
7 upper limit to the donor's weight. However, we  
8 do have limitations as regards our scales and our  
9 donor beds, on upper weight.

10 Q. What are those limitations?

11 A. I would have to look it up. I can't  
12 remember offhand what the upper limit is.

13 Q. Is the upper limit the same in all the CSL  
14 donation centers?

15 A. All of the centers use the same beds. I  
16 think there is some variation in terms of the  
17 scales, depending on when they were bought and  
18 what their upper certified limit is. I don't  
19 have that information, offhand.

20 Q. If a donor is deferred and is not  
21 satisfied with that decision, what, if anything,  
22 can they do?

23 A. The donor can ask center management  
24 to -- or the MSA to check with their CMD and see  
25 if they agree with their decision.

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1 Sometimes donors complain to the corporate  
2 office. And there is a process by which donor  
3 complaints are managed. I don't have the details  
4 on that.

5 Q. The CMD is the center medical director, is  
6 that right?

7 A. Right.

8 Q. And who do the complaints go to at  
9 corporate, if it makes it that far?

10 A. It -- it goes to a -- it goes to an office  
11 that handles donor relations. And I sometimes  
12 see a message from them that a donor has called  
13 and complained. But, for the most part, those  
14 complaints go back to the center manager to  
15 address.

16 And the center manager handles those  
17 complaints and then reports to what's called the  
18 ADOQ, assistant director for operations and  
19 quality. And the ADOQs report to what are called  
20 RDs, regional directors. Those RDs then report  
21 to the divisional operations director.

22 Q. If I understood what you were saying,  
23 occasionally a complaint that ends up at  
24 corporate might get -- if not routed to  
25 you -- sent to you for your input, perhaps,

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1 although mostly that's not the case.

2 Is that -- did I understand you correctly?

3 A. Yes.

4 Q. Okay. Is there -- if the -- start over.

5 If the donor is dissatisfied with the  
6 deferral, makes it up to corporate, and is still  
7 dissatisfied with the CSL decision, is there  
8 somewhere else there they can go or some other  
9 entity they can appeal to?

10 A. I don't know of any.

11 Simply that. I don't know of any.

12 Q. Are you aware of any process of -- for  
13 considering similar matters that the FDA might  
14 have?

15 A. If a donor complains to the FDA, I don't  
16 know what their response is. If it's a question  
17 of safety, the FDA may assign an investigator to  
18 come visit the center. If a donor complains to a  
19 state or local health department, I have, on  
20 occasion, seen the health departments  
21 investigate.

22 I have heard of donors complaining to OSHA  
23 and OSHA comes and investigates. The state and  
24 local health departments and OSHA usually go  
25 directly to the center for their investigation.

<p style="text-align: right;">Page 122</p> <p>1 Q. Can you think of any specific occasions</p> <p>2 when the FDA responded to a complaint involving</p> <p>3 CSL's donation center?</p> <p>4 A. I don't know of any specific complaint</p> <p>5 that the FDA responded to. I would probably not</p> <p>6 hear about it. All of the interaction with the</p> <p>7 FDA goes through regulatory.</p> <p>8 Q. If the -- if the person were complaining</p> <p>9 about a deferral for health re -- reasons and</p> <p>10 they felt like it was not fair or not accurate</p> <p>11 assessment of their health or safety issues,</p> <p>12 could they take that to the FDA?</p> <p>13 A. Yes. And I assume the FDA would have some</p> <p>14 process in place to respond.</p> <p>15 Q. How do you know that they could take that</p> <p>16 to the FDA?</p> <p>17 A. The FDA's mandate is ensuring the safety</p> <p>18 and effectiveness of medications, medical</p> <p>19 instruments and so on. So my simple assumption</p> <p>20 is that the FDA would have some process in place</p> <p>21 to hear complaints and respond.</p> <p>22 Q. Who at CSL would know more about that</p> <p>23 mechanism?</p> <p>24 A. I really don't know. If -- if there was a</p> <p>25 question by the FDA, it would probably be</p>	<p style="text-align: right;">Page 124</p> <p>1 line, 0001 and, down at the bottom, 0016.</p> <p>2 Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. And, if you will, look at the line 003.</p> <p>5 And it goes on to 004.</p> <p>6 And I'm reading the -- there it says,</p> <p>7 "MGMT must speak to the donor prior to his next</p> <p>8 donation. MSA MN told donor he would be unable</p> <p>9 to donate due to using a cane and walking with a</p> <p>10 limp."</p> <p>11 Did I read that correctly?</p> <p>12 A. Yes, that's read correctly.</p> <p>13 Q. And, if I understand your testimony, the</p> <p>14 use of a cane by itself would not result in a</p> <p>15 deferral, is that correct?</p> <p>16 A. The use of a cane and walking with a limp</p> <p>17 do not result in an automatic deferral.</p> <p>18 The -- and I don't know if -- when the MSA</p> <p>19 observed this, whether she told him that a health</p> <p>20 care provider note would be needed prior to his</p> <p>21 coming in to donate again.</p> <p>22 So it says that he's using a cane and</p> <p>23 walking with a limp. That -- I don't know if</p> <p>24 that was written by the MSA or whether that is</p> <p>25 what the donor told someone else and this was</p>
<p style="text-align: right;">Page 123</p> <p>1 directed to the regulatory department.</p> <p>2 Q. Let me ask you to take a look at what has</p> <p>3 been marked as Exhibit No. 2.</p> <p>4 A. I have 2 in front of me.</p> <p>5 Q. Thank you.</p> <p>6 And is this one of the documents that you</p> <p>7 looked at in preparation for your deposition here</p> <p>8 today?</p> <p>9 A. Yes. Ms. Willing presented it to me.</p> <p>10 Q. And is your understanding that these are</p> <p>11 various donor medical notes related to the</p> <p>12 plaintiff, Mark Silguero?</p> <p>13 A. That's what it says in the lower</p> <p>14 right-hand corner.</p> <p>15 Q. Okay. And are -- when you say "the lower</p> <p>16 right-hand corner," are you referring to either</p> <p>17 the Exhibit No. 2 label or the -- the number</p> <p>18 stamped below that?</p> <p>19 A. They are both there. The first column is</p> <p>20 the donor ID, but I have not looked back to</p> <p>21 confirm that this donor ID corresponds to that</p> <p>22 donor.</p> <p>23 Q. Okay. Let me -- let me point out, in the</p> <p>24 second column there are -- a numerical sequence,</p> <p>25 beginning at the top of the page. The first</p>	<p style="text-align: right;">Page 125</p> <p>1 being written third person. That's what it</p> <p>2 actually looks like, is a third person, DT, made</p> <p>3 this entry.</p> <p>4 Q. It doesn't reflect that the reporter here</p> <p>5 was the donor, correct?</p> <p>6 A. The only person -- the only people that</p> <p>7 have access to the computer, to make the notes,</p> <p>8 are CSL employees. And it appears that the</p> <p>9 employee who made this entry had the initials DT.</p> <p>10 Now, where DT got the information from,</p> <p>11 whether he got it from the MSA or whether he got</p> <p>12 it from -- this information from the donor, it's</p> <p>13 not clear to me.</p> <p>14 Q. So, looking at line three, the first part,</p> <p>15 "MGMT." Does that -- does that stand for</p> <p>16 "management"?</p> <p>17 A. Yes.</p> <p>18 Q. So it says, "Management must speak to this</p> <p>19 donor prior to his next donation."</p> <p>20 That's unlikely to have come from a donor,</p> <p>21 correct?</p> <p>22 A. That -- well, I can't tell. It sort of</p> <p>23 implies that DT made that entry, that management</p> <p>24 must speak to the donor.</p> <p>25 The second part of the line -- I don't</p>

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<p style="text-align: right;">Page 154</p> <p>1 What factual basis does CSL have for</p> <p>2 claiming that either of the plaintiffs in this</p> <p>3 case suffered no recoverable damages?</p> <p>4 A. That seems to be a legal question. The</p> <p>5 donors were not permitted to donate. As far as I</p> <p>6 know, that -- for the one person was temporary</p> <p>7 and then, because of his behavior, it became</p> <p>8 permanent.</p> <p>9 For the other donor, she is temporarily</p> <p>10 deferred.</p> <p>11 We do pay donors for their donation.</p> <p>12 However, we don't guaranty that everyone will be</p> <p>13 able to donate. So, in terms of damages, I would</p> <p>14 have to leave that up to an attorney to determine</p> <p>15 if there are recoverable damages.</p> <p>16 Q. So, just to clarify, I'm -- I'm not asking</p> <p>17 at this point for information about why CSL</p> <p>18 disputes these claims.</p> <p>19 I guess what I want to know is, does CSL</p> <p>20 have any information regarding the extent of the</p> <p>21 harm or the claimed harm that the plaintiffs</p> <p>22 suffered when they were deferred?</p> <p>23 A. The only information I have is what's in</p> <p>24 the medical notes. And I really --</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 156</p> <p>1 support the contention that plaintiff claims are</p> <p>2 within the primary jurisdiction of the FDA?</p> <p>3 A. Again, each center is licensed by the Food</p> <p>4 and Drug Administration. They have guidelines</p> <p>5 and requirements that we must follow. And all of</p> <p>6 our policies and procedures dovetail into those</p> <p>7 requirements and guidelines so that the Food and</p> <p>8 Drug Administration is the final arbiter of</p> <p>9 whether we can operate plasma centers or not.</p> <p>10 Q. You understand, though, that the</p> <p>11 plaintiffs are not contending that CSL cannot</p> <p>12 operate a plasma center. Instead, they are</p> <p>13 alleging that they were discriminated against by</p> <p>14 CSL staff.</p> <p>15 Do you see that?</p> <p>16 A. Yes. I understand that.</p> <p>17 My response would be that we do not</p> <p>18 discriminate against any class or category. Each</p> <p>19 person is assessed individually and a medical</p> <p>20 determination is made, whether they can donate or</p> <p>21 not.</p> <p>22 Q. And, as I understand it, there are no</p> <p>23 written policies or training materials that say</p> <p>24 that, is that correct?</p> <p>25 A. That say what I say?</p>
<p style="text-align: right;">Page 155</p> <p>1 A. -- can't say anything beyond that.</p> <p>2 Q. Okay. So you don't know anything about</p> <p>3 what mental anguish they may have suffered or how</p> <p>4 bad it was or anything like that --</p> <p>5 A. No. I do not --</p> <p>6 Q. -- is that correct?</p> <p>7 A. -- any information.</p> <p>8 Q. And, as far as you know, CSL does not have</p> <p>9 information about that, either, other than what</p> <p>10 might be in the testimony in this case, is that</p> <p>11 correct?</p> <p>12 A. That's correct. I know of no other</p> <p>13 information.</p> <p>14 Q. If you will turn to page 4 of this</p> <p>15 document, Exhibit 8. And I'm looking now at the</p> <p>16 subheading (1) on that page.</p> <p>17 Does CSL have any facts to support its</p> <p>18 claim that the plaintiff claims in this case are</p> <p>19 preempted by federal law?</p> <p>20 A. CSL operates under a license granted by</p> <p>21 the FDA. And that is a federal regulatory body.</p> <p>22 As a layman, in terms of law, it seems</p> <p>23 that that is a federal issue. That's all I can</p> <p>24 say about it.</p> <p>25 Q. All right. What facts does CSL have to</p>	<p style="text-align: right;">Page 157</p> <p>1 Q. Yes. There are no -- that CSL has no</p> <p>2 written policies or training components that say</p> <p>3 staff are not supposed to discriminate against a</p> <p>4 group of people?</p> <p>5 A. I don't know. There may be a policy</p> <p>6 somewhere that actually states that.</p> <p>7 Our -- my training, as a supervisor or</p> <p>8 manager, was -- has been focused primarily on</p> <p>9 employees. Perhaps there is a general statement</p> <p>10 somewhere in CSL's overall code of conduct that</p> <p>11 says we do not discriminate against donors, but I</p> <p>12 could not point you to that.</p> <p>13 Q. What facts does CSL rely on in claiming</p> <p>14 that the plaintiffs' claims are waived in this</p> <p>15 case?</p> <p>16 A. That is subitem 9 -- or (n).</p> <p>17 Q. It -- yeah. N, as in Nancy, the first</p> <p>18 part of that.</p> <p>19 A. I really have to -- these are legal terms,</p> <p>20 waiver, estoppel and unclean hands. I would have</p> <p>21 to rely on the CSL's attorney to back that</p> <p>22 statement up, but -- that's really --</p> <p>23 Q. You're not a -- I'm sorry. Go ahead.</p> <p>24 A. Yeah. I'm not an attorney, so I</p> <p>25 can't -- I don't know how to interpret that or</p>

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IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
CORPUS CHRISTI DIVISION

MARK SILGUERO,	)	
Plaintiff,	)	
	)	
and	)	
	)	
AMY WOLFE,	)	
Intervening Plaintiff,	)	
	)	
v.	)	CIVIL ACTION NO.
	)	2:16-CV-00361
CSL PLASMA INC.,	)	
DEFENDANT.	)	

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ORAL DEPOSITION OF

JULIANA SANCHEZ

JULY 7, 2017

\*\*\*\*\*

ORAL DEPOSITION of JULIANA SANCHEZ, produced as a witness at the instance of the PLAINTIFFS, and duly sworn, was taken in the above-styled and numbered cause on JULY 7, 2017, from 9:02 a.m. to 9:55 a.m., before Stephanie M. Harper, RPR, CSR in and for the State of Texas, recorded by machine shorthand, at the offices of DISABILITY RIGHT TEXAS, 1500 McGowen, SUITE 100, Houston, Texas, pursuant to the Federal Rules of Civil Procedure 30 and the provisions stated on the record or attached hereto; that the deposition shall be read and signed before any notary public.

JOB NO. 244702

U.S. LEGAL SUPPORT  
713-653-7100



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6 to 9

<p style="text-align: right;">Page 6</p> <p>1 that you will let me know; is that okay?</p> <p>2 A. Yes.</p> <p>3 Q. And if at any point you need to take a break</p> <p>4 and you need a break from the deposition, will you let</p> <p>5 me know?</p> <p>6 A. Yes, ma'am.</p> <p>7 Q. Okay. Where -- you said you're from</p> <p>8 California. What kind of background or educational</p> <p>9 certification do you have that is pertinent to your</p> <p>10 experience at CSL Plasma?</p> <p>11 A. I'm an LVN, so a licensed vocational nurse.</p> <p>12 That is what I'm -- my position is, so it's called a</p> <p>13 medical staff associate for CSL purposes, but my</p> <p>14 license is an LVN.</p> <p>15 Q. Is there any other certification or license</p> <p>16 that you hold that's pertinent to your work?</p> <p>17 A. No, ma'am.</p> <p>18 Q. And have you ever given a deposition before?</p> <p>19 A. No, ma'am.</p> <p>20 Q. What did you do to prepare for today's</p> <p>21 deposition?</p> <p>22 A. I met with Ms. Stephanie. We just went over</p> <p>23 the MSR, and --</p> <p>24 Q. I don't need you to explain anything that you</p> <p>25 talked to her about. But did you look at any</p>	<p style="text-align: right;">Page 8</p> <p>1 conversation?</p> <p>2 A. Yes, ma'am.</p> <p>3 Q. Aside from talking with Ms. Willing, did you</p> <p>4 speak with anybody else to prepare for today's</p> <p>5 deposition?</p> <p>6 A. No, ma'am.</p> <p>7 Q. Did you speak to anybody else about</p> <p>8 Ms. Wolfe's case?</p> <p>9 A. No, ma'am.</p> <p>10 Q. And are you currently employed at CSL Plasma?</p> <p>11 A. Yes.</p> <p>12 Q. And you're a medical staff associate there; is</p> <p>13 that right?</p> <p>14 A. Yes.</p> <p>15 Q. What are your job duties as a medical staff</p> <p>16 associate?</p> <p>17 A. Well, we basically look at donor candidates.</p> <p>18 We see basically if they qualify to be donors. So we</p> <p>19 look at their medical history, their physical</p> <p>20 background. We do a physical to make sure everything</p> <p>21 is acceptable for health history-wise. I also take</p> <p>22 care of reactions, donor reactions, on the donor floor.</p> <p>23 So if donors do have reactions, our medical staff does</p> <p>24 take care of it.</p> <p>25 We speak with the physicians regarding</p>
<p style="text-align: right;">Page 7</p> <p>1 documents --</p> <p>2 A. Yes.</p> <p>3 Q. -- to prepare?</p> <p>4 A. The MSR and the medical communication form.</p> <p>5 Q. And what is the "MSR"?</p> <p>6 A. It's basically the reference guidelines that</p> <p>7 the company goes by for any medical conditions or</p> <p>8 medications. That's so -- any kind of medicine or any</p> <p>9 kind of diagnosis, it has to be in there. If it's not</p> <p>10 in there, then basically they're not able to donate or</p> <p>11 we would have to refer to our physician.</p> <p>12 Q. And does the "MSR" stand for medical staff</p> <p>13 reference?</p> <p>14 A. Yes, ma'am.</p> <p>15 Q. Did you listen to anything to prepare for</p> <p>16 today's deposition?</p> <p>17 A. Yes, a video of -- like, a call recording.</p> <p>18 Q. And was it a call recording regarding what?</p> <p>19 A. When I talked to Ms. Wolfe.</p> <p>20 Q. And do you have any reason to believe that the</p> <p>21 call recording was inaccurate or not a truthful</p> <p>22 rendition of what occurred?</p> <p>23 A. It was a conversation we had between each</p> <p>24 other.</p> <p>25 Q. And did it sound like an accurate</p>	<p style="text-align: right;">Page 9</p> <p>1 any other questions we have. I also help screen. So</p> <p>2 whenever the donors get screened, I help if they need</p> <p>3 help. That's about it</p> <p>4 Q. And when you say you go over the donor</p> <p>5 history, what does that entail?</p> <p>6 A. So we ask about any surgeries, medical</p> <p>7 conditions, diagnosis. When we do the physical, we do</p> <p>8 look for any scars for surgery. We look over tattoos,</p> <p>9 see if there's any fresh tattoos, any needle marks,</p> <p>10 anything that will basically disqualify or not make the</p> <p>11 plasma quality as efficient as it should be.</p> <p>12 Q. Do you ask about past surgeries?</p> <p>13 A. Past surgeries, yes, ma'am.</p> <p>14 Q. Do you ask about future surgeries?</p> <p>15 A. Yes.</p> <p>16 Q. What kind of future surgeries do you ask</p> <p>17 about?</p> <p>18 A. Well, sometimes future surgeries, they usually</p> <p>19 voluntarily tell us. We don't usually just ask, "Oh,</p> <p>20 are you going to have a surgery next month?" If they</p> <p>21 have like a gastric surgery coming up that they know,</p> <p>22 they will let us know that they're going to have a</p> <p>23 gastric bypass. Or if they have a tooth extraction and</p> <p>24 they know they're going to be on antibiotics, they</p> <p>25 usually let us know ahead of time.</p>

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14 to 17

<p style="text-align: right;">Page 14</p> <p>1 you read over SOPs. You read over CTRs. You're</p> <p>2 questioned on what you read to see if you are</p> <p>3 knowledgeable to the information, and then you do</p> <p>4 hands-on training.</p> <p>5 Q. And do you have access to Rocio and William as</p> <p>6 part of your day-to-day job --</p> <p>7 A. If they're on the schedule, yes.</p> <p>8 Q. Who are you supposed to go to with questions</p> <p>9 on a day to day?</p> <p>10 A. It's usually more than one MSA. The only time</p> <p>11 there would be one MSA is on the weekends. If they're</p> <p>12 not there to help me out, I would contact Dr. Shafi.</p> <p>13 Q. Did you ever receive any training about donors</p> <p>14 with disabilities?</p> <p>15 A. Not directly. We do have CTRs that we read</p> <p>16 over for the training purposes for vision and hearing</p> <p>17 disability, yes.</p> <p>18 Q. And do you -- on those CTRs, did it cover</p> <p>19 other disabilities, other than vision and hearing?</p> <p>20 A. No.</p> <p>21 Q. Did you ever learn anything about disability</p> <p>22 discrimination in your trainings?</p> <p>23 A. No.</p> <p>24 Q. Do you have any knowledge of disability</p> <p>25 discrimination?</p>	<p style="text-align: right;">Page 16</p> <p>1 A. So a regulatory requirement -- we do have</p> <p>2 certain requirements that I guess are general. Some of</p> <p>3 them are -- I would say, like, if somebody has a baby,</p> <p>4 it's a six-month deferral. If anybody has IV drugs --</p> <p>5 it's just something basically that's an overall general</p> <p>6 statement for some of the regulations that they have.</p> <p>7 Q. Do you know what regulations those are</p> <p>8 referring to?</p> <p>9 A. No, ma'am.</p> <p>10 Q. And if something is not a regulatory</p> <p>11 requirement, what is that considered?</p> <p>12 A. So basically if it's not a broad -- if it's</p> <p>13 something specific, like a certain medical condition,</p> <p>14 we go by the MSR.</p> <p>15 Q. Do you use the MSR in your job every day?</p> <p>16 A. Yes, ma'am.</p> <p>17 Q. And how are you able to access the MSR in your</p> <p>18 job?</p> <p>19 A. It's in our office, our medical office.</p> <p>20 Q. And is it on in the computer or is it in</p> <p>21 paper?</p> <p>22 A. We have it in paper.</p> <p>23 Q. And do you use it on paper?</p> <p>24 A. Yes.</p> <p>25 Q. Do you use it with every donor that you</p>
<p style="text-align: right;">Page 15</p> <p>1 A. No, ma'am.</p> <p>2 Q. Have you ever had any training on something</p> <p>3 called the "Americans with Disabilities Act" or "ADA"?</p> <p>4 A. No.</p> <p>5 (Exhibit No. 6 was marked.)</p> <p>6 Q. (BY MS. DAVIS) I'm going to look at what has</p> <p>7 been marked now as Exhibit 6.</p> <p>8 A. Okay.</p> <p>9 Q. Can you tell me what this is?</p> <p>10 A. The MSR that we go by.</p> <p>11 Q. Is this the MSR that you were referencing</p> <p>12 earlier?</p> <p>13 A. Yes, ma'am.</p> <p>14 Q. And what is the effective date on this MSR?</p> <p>15 A. May 23rd of 2016.</p> <p>16 Q. And do you see on the top right-hand, it says</p> <p>17 "Page 1 of 73"?</p> <p>18 A. Yes, ma'am.</p> <p>19 Q. I'm going to be going through those pages and</p> <p>20 referring to pages on that using those numbers.</p> <p>21 A. Okay.</p> <p>22 Q. On Page 1 of 73, you see in the second</p> <p>23 paragraph, it talks about a regulatory requirement?</p> <p>24 A. Yes.</p> <p>25 Q. What does that mean, "regulatory requirement"?</p>	<p style="text-align: right;">Page 17</p> <p>1 screen?</p> <p>2 A. Yes, ma'am.</p> <p>3 Q. Do you know who wrote those guidelines?</p> <p>4 A. No.</p> <p>5 Q. Am I right to say this Rocio and William</p> <p>6 trained you on them?</p> <p>7 A. Yes.</p> <p>8 Q. Are you supposed to use your own judgment when</p> <p>9 following the guidelines?</p> <p>10 A. We go off of what is stated in the --</p> <p>11 basically, for each condition, whatever's written,</p> <p>12 whatever's acceptable, that's what we go by.</p> <p>13 Q. If it is unclear, what are you supposed to do?</p> <p>14 A. Call Dr. Shafi or MedOps.</p> <p>15 Q. If it is unclear, is it ever appropriate for</p> <p>16 you to make your own decision about what it means, what</p> <p>17 the guidelines mean?</p> <p>18 A. No.</p> <p>19 Q. If you can turn to Page 3 of 73 --</p> <p>20 MS. WILLING: You can unclip it.</p> <p>21 Q. (BY MS. DAVIS) Oh, yeah. Sorry.</p> <p>22 Do you see on this page, where there on</p> <p>23 the "If" column --</p> <p>24 A. Yes.</p> <p>25 Q. -- about one, two, three, four, five -- six</p>

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18 to 21

<p style="text-align: right;">Page 18</p> <p>1 down, it says: "Unsteady gait, falling, or dizziness"?</p> <p>2 A. Yes.</p> <p>3 Q. What is an "unsteady gait"?</p> <p>4 A. So a limp. I would just say "limp."</p> <p>5 Q. Somebody with a limp would not be allowed to</p> <p>6 donate?</p> <p>7 A. Not necessarily. We would evaluate what the</p> <p>8 limp is for. If it's for a fracture, if it's for any</p> <p>9 vision impairment, just to see exactly what is causing</p> <p>10 the limp.</p> <p>11 Q. What kind of things would cause a limp that</p> <p>12 would prohibit donation?</p> <p>13 A. Being under the influence, substance abuse,</p> <p>14 anything like that. If there's a fracture, it just</p> <p>15 depends on other conditions, as well, other</p> <p>16 qualifications.</p> <p>17 Q. What kind of conditions would cause an</p> <p>18 unsteady gait that would not prohibit?</p> <p>19 A. If there's a sprain, it's not necessarily</p> <p>20 disqualifying you. As long as there's no bruising,</p> <p>21 it's considered okay.</p> <p>22 Q. What about bad knees from obesity, if that was</p> <p>23 causing an unsteady gait, would that prohibit donation?</p> <p>24 A. That would be acceptable.</p> <p>25 Q. What would using a cane be considered; if</p>	<p style="text-align: right;">Page 20</p> <p>1 Q. If you can turn to Page -- what is marked as</p> <p>2 11 of 73 on the same exhibit, do you see where it says</p> <p>3 "Anxiety Disorders"?</p> <p>4 A. Yes, ma'am.</p> <p>5 Q. What does it say about people with anxiety</p> <p>6 disorders?</p> <p>7 A. Which column would you like?</p> <p>8 Q. I want to understand what you would -- what</p> <p>9 you would look at if you were assessing a donor. What</p> <p>10 does it say about people with anxiety disorders?</p> <p>11 How would you assess, given the information</p> <p>12 here?</p> <p>13 A. Okay. So before I would look at the MSR, I</p> <p>14 would already have the information of basically how far</p> <p>15 their anxiety goes, how long they were diagnosed, and</p> <p>16 what medications they're on. So depending on which</p> <p>17 category would apply to them, then I would look at</p> <p>18 basically the qualification for it. So depending on if</p> <p>19 they're more -- on more than two medications, if how --</p> <p>20 how often they have anxiety attacks and how long</p> <p>21 they've been diagnosed.</p> <p>22 Q. Let's start with more than two medications.</p> <p>23 How would you know if somebody was on more than two</p> <p>24 medications?</p> <p>25 A. We would have asked prior when we ask medical</p>
<p style="text-align: right;">Page 19</p> <p>1 somebody -- if a donor used a cane, would they be</p> <p>2 allowed to donate?</p> <p>3 A. Yes.</p> <p>4 Q. Can you look at the last one: "Transfer to</p> <p>5 donor bed"?</p> <p>6 A. Yes, ma'am.</p> <p>7 Q. If I'm reading that correctly, does that mean</p> <p>8 that a person is acceptable if they can transfer to and</p> <p>9 from the donor bed without assistance --</p> <p>10 A. Yes.</p> <p>11 Q. -- if they meet all other criteria?</p> <p>12 So a donor who is able to transfer safely</p> <p>13 to and from the donor bed without assistance is</p> <p>14 eligible to donate; is that right?</p> <p>15 A. Yes, as long as they don't have a problem</p> <p>16 transferring to the donor bed. Yeah.</p> <p>17 Q. Have you ever had a donor that used a cane?</p> <p>18 A. Yes.</p> <p>19 Q. And were they able to donate?</p> <p>20 A. Yes.</p> <p>21 Q. Have you ever had a donor that walked with a</p> <p>22 limp?</p> <p>23 A. Yes.</p> <p>24 Q. And were they able to donate?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 21</p> <p>1 conditions. And then we ask if they're on any</p> <p>2 medications.</p> <p>3 Q. That would have already been asked prior to</p> <p>4 getting to this point?</p> <p>5 A. Prior. Yes, ma'am.</p> <p>6 Q. Is there a specific question on the -- on the</p> <p>7 donation form that asks about anxiety disorders?</p> <p>8 A. Not anxiety specifically. When we do the</p> <p>9 physical process, we do ask about medications,</p> <p>10 diagnoses, and surgeries prior to doing any physical.</p> <p>11 Q. So if they hadn't disclosed any medications</p> <p>12 related to anxiety, would there be any way for you to</p> <p>13 know that they had anxiety?</p> <p>14 A. No.</p> <p>15 Q. And if you don't know that they have anxiety,</p> <p>16 they would still be allowed to donate because you don't</p> <p>17 have that knowledge; is that correct?</p> <p>18 A. Yes. If they didn't tell us they had the</p> <p>19 diagnosis, we would not know.</p> <p>20 Q. And what about a service animal; what does it</p> <p>21 say about a service animal?</p> <p>22 A. Relating to anxiety disorders, it just says</p> <p>23 for service animal guidelines, if unclear, contact</p> <p>24 MedOps. So it says to refer to a separate CTR number.</p> <p>25 Q. And so if you were to get -- if you were to</p>

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22 to 25

<p style="text-align: right;">Page 22</p> <p>1 look at this with somebody who had a service animal, 2 what would you do? 3 What would be your typical course of action? 4 A. So first, I would look at the CTR02121 and see 5 what that stated. And then if that did not answer my 6 question, I would call MedOps, just as stated. 7 Q. And would you do that while the person was 8 there -- while the donor was there with you? 9 A. Yes. 10 Q. Walk me through what that looks like. If the 11 donor's sitting there with you, and you had to go 12 through this process, what would you do? 13 A. So usually I -- I look at this in front of 14 them. I explain to them what it says, and then I would 15 tell them to wait a second so I could pull up the other 16 CTR number. I would read over that CTR. If that's 17 unclear, I would tell them, "This doesn't really 18 explain specifically what I should do, so my other 19 option is to call Ops." 20 MedOps sometimes does not always answer. 21 So in that case instead of having them wait because it 22 could take a couple of hours, we are allowed to let 23 them leave the facility, enter their information, and 24 then recontact them. 25 Q. And would you look up the CTR while the donor</p>	<p style="text-align: right;">Page 24</p> <p>1 diagnosis. 2 Q. So even if they say they think they have 3 anxiety -- 4 A. When it's a possibility, we still send them 5 with the HCP letter, just so we can have a 6 confirmation. 7 Q. What is the "HCP letter"? 8 A. It's basically a letter we give out anytime 9 that we need additional information to any diagnosis, 10 if people have high blood pressure continuously but are 11 not on any medications, and we want them to seek 12 further evaluation before continuing donating. 13 Q. What does "HCP" stand for? 14 A. Health consent form. 15 Q. So even if a person is just saying "I think I 16 have anxiety," that's the end of their donation; is 17 that correct? 18 A. If they say they think they have anxiety, we 19 usually tell them that they should be evaluated before 20 continuing. So it -- it's not necessarily they stop 21 donating completely, but before they can continue, they 22 would need to seek medical care. 23 Q. The donation that day -- 24 A. Yes, ma'am. 25 Q. -- will end?</p>
<p style="text-align: right;">Page 23</p> <p>1 was sitting there with you -- 2 A. Yes. 3 Q. -- or would you leave the room? 4 A. No, while they're sitting there waiting for -- 5 with me in the room. 6 Q. Okay. So that information is accessible to 7 you there in the room with the donor? 8 A. Yes. 9 Q. And if someone didn't have a service animal 10 but had anxiety, would you have any way of knowing that 11 they had anxiety? 12 A. If they did not disclose it, no. 13 Q. Have you ever had a donor who had anxiety that 14 they did not disclose? 15 A. If they didn't disclose it, I wouldn't know. 16 Q. So have you ever found out after the fact? 17 A. After the fact, yes. When we do vitals, some 18 people with anxiety, their vitals do tend to be a 19 little higher. Pulses usually -- usually do tend to be 20 a little higher, and that's just medically. 21 Q. And were they still allowed to donate? 22 A. Once we ask sometimes why their pulse -- they 23 usually come out and disclose, "Well, I have" -- "I 24 think I have anxiety." And when something like that -- 25 we usually send them to see a physician so we can get a</p>	<p style="text-align: right;">Page 25</p> <p>1 A. Um-hmm. 2 Q. How -- in what other circumstances do you give 3 out the HCP letters? 4 A. So for vitals like high blood pressure, high 5 pulse continuously. If people have low hematocrit 6 levels. If we think they're anemic. If they say that 7 they have a medical condition, but they're not sure 8 what medications they're on, we usually send an HCP 9 letter so their physician can tell us exactly what 10 medications they are taking. 11 Q. Do you give out information to donors about 12 their vitals? 13 A. Yes. 14 Q. Do you tell them their vitals? 15 A. Yes. 16 Q. Do you tell them their hematocrit? 17 A. Yes. 18 Q. Do you explain to them why those may be what 19 they are? 20 A. Yes. 21 Q. And maybe how they can improve those levels? 22 A. Yes. 23 Q. You provide that health information to -- 24 A. Every donor. 25 Q. Every donor.</p>

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26 to 29

<p style="text-align: right;">Page 26</p> <p>1 Are you also the person that tells potential</p> <p>2 donors that they would be deferred?</p> <p>3 Does that information come from you?</p> <p>4 A. Not always.</p> <p>5 Q. Who else would it come from?</p> <p>6 A. There are other receptionists that screen</p> <p>7 donors. The only time -- if I'm the one putting the</p> <p>8 donor in the system, then I would be the person telling</p> <p>9 them they are deferred. But it is a different set of</p> <p>10 group of people all the time.</p> <p>11 Q. So if you're doing the screenings, does that</p> <p>12 mean that you would be the person to tell them that</p> <p>13 they are deferred?</p> <p>14 A. For that -- for each donor, yes.</p> <p>15 Q. The person that does the screening is the</p> <p>16 person that typically does the deferral; is that how</p> <p>17 I'm understanding it?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. Would you tell donors why they were</p> <p>20 being deferred?</p> <p>21 A. Yes.</p> <p>22 Q. What happens after someone gets deferred from</p> <p>23 your side of the job?</p> <p>24 A. Can you rephrase that?</p> <p>25 Q. Do you put that in the computer?</p>	<p style="text-align: right;">Page 28</p> <p>1 Q. Do -- do they threaten to talk with your</p> <p>2 supervisor ever?</p> <p>3 A. Yes.</p> <p>4 Q. Do they get to talk with your supervisor?</p> <p>5 A. Yeah.</p> <p>6 Q. Is that your job to refer them to your</p> <p>7 supervisor?</p> <p>8 A. Yes.</p> <p>9 Q. Does the supervisor ever overturn the reason</p> <p>10 for deferral?</p> <p>11 A. No.</p> <p>12 Q. What if the person being deferred can prove</p> <p>13 that the reason for deferral was incorrect?</p> <p>14 A. It just depends on the situation. Every</p> <p>15 situation is different. Some people say they had --</p> <p>16 they were incarcerated for a certain amount of time,</p> <p>17 and then once they realize the deferral period is so</p> <p>18 long, they go back and say, "Okay, well, I wasn't</p> <p>19 incarcerated for that long." So when something like</p> <p>20 that happens, we ask them to bring court documentation</p> <p>21 proving the days, and then it can be overturned. So it</p> <p>22 just depends on each situation.</p> <p>23 Q. There is an opportunity potentially for them</p> <p>24 to bring documentation in to prove the reason is</p> <p>25 incorrect?</p>
<p style="text-align: right;">Page 27</p> <p>1 After someone gets deferred, what do you do</p> <p>2 with that information?</p> <p>3 A. Yes, we document it in their file.</p> <p>4 Q. Do you document in the file why there was a</p> <p>5 deferral?</p> <p>6 A. Yes.</p> <p>7 Q. And do you document in the file what could be</p> <p>8 done to change the deferral's decision?</p> <p>9 A. Not necessarily. We don't put what could be</p> <p>10 done to change deferral. We can -- we usually put --</p> <p>11 say, if there's a tattoo, for example, they just had a</p> <p>12 tattoo, we put when the deferral would be lifted, yes.</p> <p>13 Q. Can donors disagree with the reason for being</p> <p>14 deferred?</p> <p>15 A. As in...</p> <p>16 Q. If a donor disagrees with the reason for the</p> <p>17 deferral, can they tell you that they disagree?</p> <p>18 A. They can tell us they disagree. If it's our</p> <p>19 corporate policy, we just go by the policy. We explain</p> <p>20 them -- to, like, the best of our ability. Try to have</p> <p>21 them understand and be aware of why we're deciding.</p> <p>22 But if it's medically in writing, we don't go against</p> <p>23 it.</p> <p>24 Q. Do donors ever get angry about being deferred?</p> <p>25 A. All the time. Most of the time.</p>	<p style="text-align: right;">Page 29</p> <p>1 A. Yes.</p> <p>2 Q. Do you remember Ms. Wolfe?</p> <p>3 A. Yes.</p> <p>4 Q. What do you remember about her?</p> <p>5 A. I remember when she had walked in, we were</p> <p>6 really busy that day. She was trying to be a potential</p> <p>7 donor. And I was the MSA that had took care of her.</p> <p>8 Q. What else do you remember about her?</p> <p>9 A. She did have her service animal with her.</p> <p>10 Q. Is there anything else that you remember about</p> <p>11 her?</p> <p>12 A. No.</p> <p>13 Q. She was pretty unremarkable?</p> <p>14 A. She was quiet.</p> <p>15 Q. Had you ever seen a service animal before?</p> <p>16 A. Yes.</p> <p>17 Q. At CSL Plasma?</p> <p>18 A. No, not at CSL.</p> <p>19 Q. Have you had any donors before that had a</p> <p>20 service animal?</p> <p>21 A. No.</p> <p>22 Q. So this was an issue that you had never dealt</p> <p>23 with before?</p> <p>24 A. No.</p> <p>25 Q. A donor with a service animal?</p>



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30 to 33

<p style="text-align: right;">Page 30</p> <p>1 A. Yeah, I had never had a donor with a service 2 animal. 3 Q. Did you talk to anybody that day about Miss -- 4 Ms. Wolfe and her service animal? 5 A. I -- I don't remember who was at the front 6 counter, but I -- they did tell me to take care of her. 7 So I took her into the medical office just so she 8 wouldn't be waiting because I didn't know exactly what 9 the guidelines were. So that's why I went and checked 10 myself, other than MedOps, which was Dr. Nelson, no. 11 Q. And you took her into the front office? 12 A. Into the medical office. 13 Q. Into the medical office, which was in the 14 front? 15 A. It's MSA 1. It's kind of in a hallway. 16 Q. Okay. And then what happened? 17 A. I sat her down. I created her profile, just 18 so I could have everything in documentation, just so I 19 can contact Dr. Nelson and I can put everything in her 20 notes. I did look at the MSR. I asked her what her 21 diagnosis was. She did say her diagnosis was for 22 anxiety and PTSD, and she stated she wasn't on any 23 medications. And then from there, I just looked at the 24 guidelines. 25 Q. When you first saw the service animal, did you</p>	<p style="text-align: right;">Page 32</p> <p>1 A. Not that I remember. 2 Q. Other than the guidelines that you located, 3 does CSL Plasma have any other guidelines about service 4 dogs? 5 A. They allow service dogs for vision and hearing 6 impairment. 7 Q. Do you know why they allow service dogs for a 8 visual or hearing impairment, but not for anxiety 9 disorder? 10 A. Because it's not necessarily the service dog 11 that is the disqualifying. It is the disorder. 12 Because the service dog is needed. It's visualized as 13 a severe or frequent reaction. 14 Q. Have you ever had a donor have a reaction on 15 the don- -- donation floor? 16 A. Yes. 17 Q. What happened? 18 A. They can have seizures, lose consciousness, 19 get dizzy, vomit, nausea. 20 Q. Have you ever had a donor have an anxiety 21 reaction on the donor floor? 22 A. Some of the reactions start from anxiety, 23 anxiety to the needles, which will cause them to have 24 those symptoms. 25 Q. After you -- after the donor had that</p>
<p style="text-align: right;">Page 31</p> <p>1 already know what the guidelines said? 2 A. No. 3 Q. You looked them up that day? 4 A. Yes. 5 Q. What did Ms. Wolfe say to you that day? 6 A. I don't remember. 7 Q. Did she ask you if she seemed anxious? 8 A. I don't remember. 9 Q. Do you remember if she seemed anxious that 10 day? 11 A. She was calm. 12 Q. If she hadn't had her service animal with her, 13 was there anything about what she was doing that would 14 have alerted you to her anxiety? 15 A. No. 16 Q. So the service animal was the only thing that 17 made you know that she was anxious -- 18 A. No, her verbally -- 19 Q. -- or that she had anxiety? 20 A. Her verbally telling me that she had anxiety. 21 Q. But otherwise, was there anything else that 22 she did that made you think she had anxiety? 23 A. No. 24 Q. Did she tell you how the service dog helped 25 her?</p>	<p style="text-align: right;">Page 33</p> <p>1 reaction, did you then ask them about an anxiety 2 disorder? 3 A. No. 4 Q. Were they allowed to donate in the future? 5 A. That is up to Dr. Shafi. Any kind of reaction 6 is put in the notes. It's documented as a donor 7 adverse event, and Dr. Shafi goes over everything. If 8 she feels the need to speak to the donor, she would 9 speak to the donor, reevaluate, and assess if they're 10 allowed to donate or not. 11 Q. So there have been donors who had an adverse 12 event and later donated again -- 13 A. Yes. 14 Q. -- is that right? 15 Did Ms. Wolfe offer to leave her service 16 dog outside during the donation? 17 A. Not -- not outside. In the building, I 18 believe in the waiting room, she had said. 19 Q. In the waiting room? 20 A. We have like a little waiting area, yes, 21 ma'am. 22 Q. If Ms. Wolfe had not had her service dog with 23 her that day, would she have been able to donate, 24 assuming she met all other criteria? 25 A. If she met all the other criteria.</p>

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34 to 37

<p style="text-align: right;">Page 34</p> <p>1 Q. Did she do anything that made you concerned 2 about her ability to donate? 3 A. From the little time I spoke to her, no. 4 Q. Did you talk to any other staff members aside 5 from Dr. Nelson about Ms. Wolfe and her service dog 6 after she left that day? 7 A. No. 8 Q. Did it seem unusual for you to see a service 9 dog? 10 Was that something that you wanted to share 11 with other people at the -- at the office? 12 A. No. We have some stuff that always happens. 13 It's always something new every day. 14 Q. Do you know why there was a recommendation to 15 defer Ms. Wolfe? 16 A. Just due -- because they figured that her 17 anxiety because of the service dog was severe. She 18 wasn't on any medications, so that was Dr. Nelson's 19 choice. 20 Q. Could you tell if it was anybody else's 21 decision, other than Dr. Nelson's? 22 A. No. 23 Q. Did Dr. Nelson ask you anything about 24 Ms. Wolfe? 25 A. Just asked me how long she had anxiety, what</p>	<p style="text-align: right;">Page 36</p> <p>1 A. Not from my experience, no. 2 Q. Have you ever had a donor appear anxious? 3 A. Yes. 4 Q. How did you know they were anxious? 5 A. They usually fidget. They get sweaty. Vitals 6 are usually not in the range. It's usually just -- 7 you -- you can see it physically. Signs that you 8 observe. 9 Q. And are you supposed to ask about that when 10 you observe it? 11 A. Yes. 12 Q. What do you ask? 13 A. We ask them if everything is okay. If 14 anything is making them stressed. We can have the 15 ability to take them in our medical office and examine 16 and go into further detail and ask what is making them 17 stress. If they're on any kind of substance abuse 18 because sometimes that could be the reason why they're 19 fidgeting. We are allowed to check pupillary reaction 20 to see if they are on any substance because that 21 usually will show us some kind of sign. 22 Q. And then depending on what you discovered 23 because of what you observed, would you then make a 24 decision about whether or not that donor could donate 25 that day?</p>
<p style="text-align: right;">Page 35</p> <p>1 other diagnosis she had, and if she was on any 2 medications. 3 Q. How did you answer those questions? 4 A. I told him that she had anxiety since 5 childhood. She recently had -- P- -- PTSD. I don't 6 remember for how many years I said exactly due to a 7 trauma she had, and she said she was currently on no 8 medications. 9 Q. Did he ask anything about how the service 10 animal helped her? 11 A. No. 12 Q. Did he ask any follow-up questions about the 13 PTSD? 14 A. Not that I remember. 15 Q. Any follow-up questions about the anxiety? 16 A. Not that I remember. 17 Q. Approximately, probably, how long was your 18 phone call with Dr. Nelson? 19 A. I had to leave a voicemail. He returned my 20 call. 21 Q. And how long was the call that he returned? 22 A. Maybe less than five minutes. 23 Q. And you've never had someone who has a guide 24 dog or who's blind donate plasma, is that right, 25 with -- with a service dog?</p>	<p style="text-align: right;">Page 37</p> <p>1 A. Yes. 2 Q. Did you ask Ms. Wolfe any sym- -- about her 3 symptoms of anxiety? 4 A. I don't remember. 5 Q. Were you supposed to ask about her symptoms of 6 anxiety? 7 A. We usually do. She said she had anxiety since 8 childhood, so I don't really remember if I asked or 9 not. I usually do ask what their symptoms are, how 10 frequent, if they've had any kind of reactions or any 11 anxiety attacks. 12 Q. And do you remember if she answered any of 13 those questions? 14 A. I don't remember because I don't remember if I 15 had asked or not. 16 Q. How did you describe Ms. Wolfe to Dr. Nelson? 17 A. As a donor that was trying to donate. That 18 she had an anxiety disorder, anxiety diagnosis, PTSD 19 diagnosis. Basically just information she told me. 20 Other than that, there was nothing else. 21 Q. Do you have any reason to believe that 22 Ms. Wolfe does not have a disability? 23 A. No. 24 Q. Do you have any reason to believe that her 25 service dog is not a service dog?</p>

Juliana Sanchez  
July 07, 2017

42 to 45

<p style="text-align: right;">Page 42</p> <p>1 This is what's actually on her comments on her file.</p> <p>2 Q. And if you were accessing her file, would you</p> <p>3 be able to get the medical communication form, too?</p> <p>4 A. Yes.</p> <p>5 Q. But they're considered separate documents, the</p> <p>6 medical communication form and these medical notes?</p> <p>7 A. Yes.</p> <p>8 Q. And are the notes that are here on Houston</p> <p>9 Center 0143, on both -- both lines, do they look like</p> <p>10 an accurate description of what happened with your</p> <p>11 communication with Dr. Nelson?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. On the next page, -000328, at the</p> <p>14 bottom right, what is this?</p> <p>15 A. This is a screenshot from the computer of what</p> <p>16 the medical notes looks like on the Web site.</p> <p>17 Q. So essentially, one is what the printout looks</p> <p>18 like, and the other is what it would look like on the</p> <p>19 computer screen?</p> <p>20 A. Um-hmm. Yes, ma'am.</p> <p>21 Q. Dr. Nelson, per your notes, had said that if</p> <p>22 service dog is no longer necessary, then she would be</p> <p>23 eligible to donate. Who would decide if the service</p> <p>24 dog was no longer necessary?</p> <p>25 A. We would send an HCP letter for her to get</p>	<p style="text-align: right;">Page 44</p> <p>1 supervisor?</p> <p>2 A. Yes.</p> <p>3 Q. Are those different departments?</p> <p>4 A. Yes.</p> <p>5 Q. And so what does the medical operations</p> <p>6 supervisor do?</p> <p>7 A. He's kind of over all the MSAs. He recently</p> <p>8 got promoted, so I'm not sure if at the time he was</p> <p>9 MOS. Before it was Rocio, but she had just had a baby.</p> <p>10 She was on maternity leave. So I don't remember if she</p> <p>11 was out on maternity leave at the time that all this</p> <p>12 happened.</p> <p>13 Q. Please look at what has been titled Exhibit 6.</p> <p>14 And do you see on Page 3 of 73, at the</p> <p>15 bottom, do you see the transfer to the donor bed?</p> <p>16 A. Yes.</p> <p>17 Q. I believe you said earlier that if someone</p> <p>18 transfers to the donor bed doesn't have a problem doing</p> <p>19 so, they'd be able to donate, assuming that they met</p> <p>20 all other criteria. What do you mean, "doesn't have a</p> <p>21 problem"? What would be a problem transferring to a</p> <p>22 donor bed?</p> <p>23 A. So over here, it's transferring to the donor</p> <p>24 bed, and it has to do with the disability. So say if</p> <p>25 there's a vision disability and they need somebody to</p>
<p style="text-align: right;">Page 43</p> <p>1 filled out from her psychiatrist --</p> <p>2 Q. And it --</p> <p>3 A. -- or her therapist.</p> <p>4 Q. It would require that she have a letter from</p> <p>5 her phys- -- physician or -- or counselor or therapist</p> <p>6 to state that the service animal was no longer</p> <p>7 necessary?</p> <p>8 A. Yes, ma'am.</p> <p>9 Q. Okay.</p> <p>10 MS. DAVIS: I'd like to take a brief</p> <p>11 break and go off the record.</p> <p>12 (Break from 9:44 a.m. to 9:52 a.m.)</p> <p>13 Q. (BY MS. DAVIS) You mentioned the medical ops</p> <p>14 earlier. What is the "medical ops"?</p> <p>15 A. It's a hotline -- not necessarily a hotline,</p> <p>16 but a list of numbers that you could call. So it's the</p> <p>17 different physicians that they have just in case we're</p> <p>18 not able the reach our center physician.</p> <p>19 Q. And did I understand that -- that William went</p> <p>20 to medical ops?</p> <p>21 A. He's a medical ops supervisor. So it's</p> <p>22 medical operations supervisor, is what it stands for.</p> <p>23 It's just kind of like he's over all the MSAs now.</p> <p>24 Q. Okay. So explain this a little bit more.</p> <p>25 There's the medical ops and then the medical operations</p>	<p style="text-align: right;">Page 45</p> <p>1 put them physically on the donor bed and take them</p> <p>2 physically off, that would be something that would</p> <p>3 disqualify them. They have to be able to sit down by</p> <p>4 themselves independently and get up independently.</p> <p>5 There is a small space in between the beds, so it's</p> <p>6 just a safety risk.</p> <p>7 Q. And if they used a -- a cane to assist them</p> <p>8 getting on and off the donor bed, would that mean that</p> <p>9 they were still acceptable if they met all other</p> <p>10 criteria?</p> <p>11 A. By experience, we do have donors that use</p> <p>12 canes, so I would say yes.</p> <p>13 Q. When you left Dr. Nelson a voicemail regarding</p> <p>14 Ms. Wolfe, what did you say on the voicemail?</p> <p>15 A. I don't remember exactly.</p> <p>16 Q. What type of information generally would you</p> <p>17 have included in the voicemail about Ms. Wolfe?</p> <p>18 A. We usually state who's calling, where we're</p> <p>19 calling from, what our question is. So I'm sure I</p> <p>20 would say what the donor is calling for or what they're</p> <p>21 coming in for and the reason we need extra information.</p> <p>22 So we usually we'll explain the situation.</p> <p>23 Q. In this case, what would you -- what did you</p> <p>24 tell Mr. Nelson, to the best of your recollection?</p> <p>25 A. I don't remember what I said.</p>

Page 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
CORPUS CHRISTI DIVISION

MARK SILGUERO,  
Plaintiff,

§ 87(2)(b)

and

AMY WOLFE,  
Intervening Plaintiff,

CIVIL ACTION  
NO. 2:16-CV-00361

v.

CSL PLASMA INC.,  
Defendant.

ORAL DEPOSITION OF

SAM SCHULTZ

April 10, 2017

ORAL DEPOSITION OF SAM SCHULTZ, produced as a witness at the instance of the Plaintiff, and duly sworn, was taken in the above-styled and numbered cause on the 10th of April 2017, from 2:25 p.m. to 4:12 p.m., before Isabel Connor, CSR in and for the State of Texas, reported by machine shorthand, at the offices of U.S. Legal Support, 802 North Carancahua Street, Suite 2280, Corpus Christi, Texas, pursuant to the Federal Rules of Civil Procedure.

Sam Schultz  
April 10, 2017

10 to 13

<p style="text-align: right;">Page 10</p> <p>1 A. -- Paramedic.</p> <p>2 Q. How long did that -- I'm sorry.</p> <p>3 A. That's okay. I was trying to think of the rest</p> <p>4 of the name.</p> <p>5 Q. How long did that course of study take?</p> <p>6 A. I believe it was about eight months, maybe</p> <p>7 nine.</p> <p>8 Q. Have you ever had a job as a paramedic?</p> <p>9 A. Yes, sir.</p> <p>10 Q. For whom?</p> <p>11 A. Gold Cross Ambulance.</p> <p>12 Q. Any other position as a paramedic?</p> <p>13 A. No, sir.</p> <p>14 Q. And how long did you have the Gold Cross job?</p> <p>15 A. I worked at Gold Cross for almost seven years.</p> <p>16 Q. Was that in Utah or here --</p> <p>17 A. Yes, sir.</p> <p>18 Q. -- in Texas?</p> <p>19 A. In Utah.</p> <p>20 Q. And what brought you to Texas?</p> <p>21 A. CSL.</p> <p>22 Q. How did you find out about the job?</p> <p>23 A. I don't recall.</p> <p>24 Q. And I apologize if I asked you before. What</p> <p>25 was your -- the date that you started at CSL?</p>	<p style="text-align: right;">Page 11</p> <p>1 A. Believe it was in June of 2014.</p> <p>2 Q. I did ask you before. Sorry. All right.</p> <p>3 Other than what you've already told us, do you have any</p> <p>4 education or other training after high school?</p> <p>5 A. After high school?</p> <p>6 Q. Yes.</p> <p>7 A. I was in the Marines for four years.</p> <p>8 Q. All right.</p> <p>9 A. -- take leadership courses in the Marines.</p> <p>10 Q. Did you specialize in any particular area in</p> <p>11 the Marines that is sort of transferable to civilian</p> <p>12 life?</p> <p>13 A. Not -- not directly. And my MOS was -- was</p> <p>14 artillery. But I was a manager, if you will. I was a</p> <p>15 platoon sergeant, so similar role.</p> <p>16 Q. Have you had any other work experience that you</p> <p>17 believe is relevant to your current job at CSL that</p> <p>18 you -- besides what you've already told us?</p> <p>19 A. Not that I can think of right now.</p> <p>20 Q. We have seen reference in this case to an</p> <p>21 individual named Tammy Brown, who I -- if I understand</p> <p>22 correctly, was some kind of trainer. Do you know</p> <p>23 Ms. Brown?</p> <p>24 A. I do.</p> <p>25 Q. Was she working for CSL when you were there?</p>
<p style="text-align: right;">Page 12</p> <p>1 A. Yes.</p> <p>2 Q. And am I correct that she no longer works for</p> <p>3 CSL?</p> <p>4 A. Correct.</p> <p>5 Q. And what was her job when she was last there?</p> <p>6 A. She was training coordinator.</p> <p>7 Q. What does that mean?</p> <p>8 A. Essentially they would be in charge of</p> <p>9 training, assigning, documenting, or learning initial</p> <p>10 part of the training, new hire, orientation, etc.</p> <p>11 Q. All right. Do you know why she left CSL?</p> <p>12 A. I don't.</p> <p>13 Q. Was she terminated by CSL?</p> <p>14 A. No. It was voluntary.</p> <p>15 Q. Are you in contact with her now?</p> <p>16 A. No, sir.</p> <p>17 Q. Do you know where she is?</p> <p>18 A. I do not, sir.</p> <p>19 Q. We also saw reference to an individual named, I</p> <p>20 believe, Dennis Thomas. And I think he was reflected as</p> <p>21 perhaps an assistant manager. Is that right?</p> <p>22 A. Yes, sir.</p> <p>23 Q. And am I right that he no longer works for CSL?</p> <p>24 A. Correct.</p> <p>25 Q. Do you know why he left CSL?</p>	<p style="text-align: right;">Page 13</p> <p>1 A. I do not.</p> <p>2 Q. Was he terminated?</p> <p>3 A. I don't know.</p> <p>4 Q. Okay.</p> <p>5 A. He transferred from my center.</p> <p>6 Q. And where did he go to?</p> <p>7 A. I don't know that either.</p> <p>8 Q. So if I understand you correctly, he moved</p> <p>9 from -- he stayed at CSL but moved to another location,</p> <p>10 and then you lost track of him?</p> <p>11 A. Yes, sir.</p> <p>12 Q. All right. Could you describe for me the</p> <p>13 plasma donation process from the point of view of the</p> <p>14 customer. So if they've never donated before and they</p> <p>15 walk in the door, sort of what happens?</p> <p>16 A. They have to go through a new donor process,</p> <p>17 which is different than a return donor process. That</p> <p>18 involves some additional information, reading, watching a</p> <p>19 video. They get entered into our database.</p> <p>20 Then they go through the normal</p> <p>21 prescreening process that every donor, every time they</p> <p>22 come in, will go through. Then they have a health</p> <p>23 assessment. And then they get taken to the floor where</p> <p>24 they go through the plasmapheresis procedure.</p> <p>25 Q. And you indicated that the prescreening is</p>



Sam Schultz  
April 10, 2017

46 to 49

<p style="text-align: right;">Page 46</p> <p>1 date of the event that is described on the note. Is 2 that -- am I right about that? 3 A. That looks to be correct. 4 Q. And am I also right that this doesn't 5 necessarily reflect every donation this person made, but 6 instead reflects the donations for which there were 7 medical notes? 8 A. Yes. 9 Q. So there might be donations this person made, 10 and there were no medical notes, and it wouldn't be on 11 this list? 12 A. Correct. This -- this is not a list of 13 donations. 14 Q. All right. All right. So if I can call your 15 attention to the third and fourth and fifth lines on this 16 page. So there is a column -- the second column says 17 donor medical SEQ. 18 And those are sort of -- we'll use those 19 because they're sequential. We'll use those as line 20 numbers, all right? 21 A. Yes, sir. 22 Q. So I'm talking about lines 3, 4, and 5. And 23 those all seem to relate to an event that happened on 24 January 2nd, 2015, according to the next to last column; 25 is that right?</p>	<p style="text-align: right;">Page 47</p> <p>1 A. Yes. 2 Q. What is your understanding from these notes of 3 what that reflects? 4 A. The notes look like it was initially requested 5 to speak to a manager prior to further donations, based 6 on the comment that was made. 7 Q. And so on the third line, it says, management 8 must speak to this donor prior to his next donation. 9 Correct? 10 A. Yes. 11 Q. And then it says MSA MM told donor he would be 12 unable to donate due to using a cane and walking with a 13 limp. 14 Stop there. There's a period. MSA is the 15 position title you've described generally. Do you know 16 who the MSA MM was or is? 17 A. The -- the name Michelle Mailey, yes. 18 Q. Okay. So let's just -- just talking about that 19 information there, that statement there beginning with 20 MSA MM and ending with walking with a limp, do you know 21 anything more about what happened on that event or what 22 she observed on that event other than what's listed 23 there? 24 A. No, sir. 25 Q. Okay. Have you ever talked to her about that?</p>
<p style="text-align: right;">Page 48</p> <p>1 A. No, sir. 2 Q. And if I am recalling correctly, you were not 3 at the Ayers facility when this happened? 4 A. That is correct. 5 Q. And then reading on at the end of where we left 6 off -- so this is beginning on the fourth line, yes -- he 7 told her that she, quote, would regret this, and left. 8 And then initials DT, 1/2/2015. 9 Do you know anything more about what is 10 described there other than what's in the words? 11 A. No. 12 Q. Do you know who DT is? 13 A. Dennis Thomas. 14 Q. Have you ever had occasion to talk to Dennis 15 Thomas about what might have happened with regard to 16 Mr. Silguero? 17 A. No. 18 Q. Ever had occasion to talk to Michelle Mailey 19 about what might have happened with regard to 20 Mr. Silguero? 21 A. No. 22 Q. All right. Let me ask you to look at the 23 second line. And tell me what that says and what you 24 understand that means. 25 A. It has a date, and then it says donor is</p>	<p style="text-align: right;">Page 49</p> <p>1 permanently rejected for threatening staff. And then 2 initials and date. 3 Q. And do you know who TMB is? 4 A. I believe that is Tammy Brown. 5 Q. Can you -- well, do you know anything more 6 about the incident described here other than what's 7 written down here? 8 A. No. 9 Q. Have you ever talked to Tammy Brown about this 10 incident? 11 A. No. 12 Q. Can you tell if the -- threatening the staff is 13 referring to the -- she-would-regret-this note a few 14 lines below? Can you tell if that's the same thing or 15 something different? 16 A. It's reasonable to assume that the next 17 sequential one that would be there would be for the most 18 recent one. But, no, I don't know specifically that 19 that's related to that. 20 Q. All right. And -- and I guess from your 21 answer, that also means that when that second line refers 22 to January 3rd, 2015, you don't know if that meant there 23 was a threat on that date or if that's the documentation 24 of some earlier comment from the day before? 25 A. Correct.</p>

Sam Schultz  
April 10, 2017

50 to 53

<p style="text-align: right;">Page 50</p> <p>1 Q. All right. And then the first entry, so on the 2 first line of this page, the date is 4/7 of '15. What 3 does that say, and what does that mean to you? 4 A. Said, called donor and left a message and the 5 initials and date. 6 Q. Do you know what that means? 7 A. That they called and left a message. 8 Q. Do you know who called? 9 A. It looks like Nola Baker. 10 Q. And what was -- at that point what was 11 Mr. Baker's position? 12 A. She's my assistant manager. 13 Q. I'm sorry. Is it Nola? 14 A. Nola, yes. 15 Q. How do you spell that? 16 A. N-o-l-a. 17 Q. All right. Apologize. So at that time in 18 April of 2015, she was also an assistant manager, to -- 19 A. Yes. 20 Q. -- your understanding? All right. Do you know 21 anything more about what's referenced on that first line 22 other than what's on the page? 23 A. No, sir. 24 Q. Have you ever had occasion to talk to Ms. Baker 25 about Mr. Silguero or anything related on this page?</p>	<p style="text-align: right;">Page 51</p> <p>1 A. No, sir. 2 Q. Do you know if CSL is currently prohibiting 3 Mr. Silguero from donating? 4 A. Do I know? 5 Q. Yes. 6 A. There is a deferral on his account, yes. 7 Q. All right. So if he were to come in at this 8 point and try to donate, he would be told not -- not to? 9 A. Currently, yes. 10 Q. And when you were reading that exhibit -- and 11 it was on line -- the second line, it said, donor PR'd 12 for threatening staff. And I think you said something 13 like permanently denied. 14 A. And so I'm just -- I want to make sure I 15 understand, is PR, apostrophe D -- is that permanently 16 denied or permanently deferred or -- 17 A. Permanently deferred. Stands for permanently 18 rejected. 19 Q. Okay. The lawsuit that we're here about today 20 stems from the incident that happened on or about 21 January 2nd, 2015. That is partly referenced in those 22 notes you were looking at. 23 Do you know anything else about that 24 incident other than what you've told us or what you've 25 read?</p>
<p style="text-align: right;">Page 52</p> <p>1 A. No, sir. 2 Q. Okay. Have you ever talked to anybody else -- 3 start over. Aside from lawyers, legal representatives 4 for CSL, have you ever talked to anybody else about that 5 incident? 6 A. No, sir. 7 Q. Have -- during your tenure, either as assistant 8 manager in Fort Worth or as the manager in Corpus, has 9 anybody ever been rejected or refused or deferred for 10 threatening staff? 11 A. Yes, sir. 12 Q. Give me an example of the kind of threats that 13 you've been aware of. 14 A. Had a bomb threat. Had an individual threaten 15 to have a shootout in the parking lot with the police 16 officers. I've had people make sexual advances on 17 employees, both males and females, excessive profanity, 18 yelling, cursing, threats -- threats of violence. Better 19 not meet me in the parking lot, things like that. 20 Q. How frequently does that happen? 21 A. Several times a month probably, at my locations 22 anyway. 23 Q. When that happens, other than noting the 24 deferral in your -- in your recordkeeping, does your 25 office or does CSL take any other action?</p>	<p style="text-align: right;">Page 53</p> <p>1 A. Not to my knowledge. 2 Q. Do you ever contact law enforcement about those 3 matters? 4 A. I have, yes. 5 Q. When would you do that? 6 A. The gentleman that threatened to have a 7 shootout in the parking lot, if they're threatening 8 violence or have attempted violence. I've had people 9 take a swing at me before. If they're causing a scene 10 and -- and are refusing to leave the building, yes, we 11 have. 12 Q. Is -- when law enforcement is contacted by CSL, 13 is that always done by you or might it be done by other 14 staff? 15 A. It could be done by other staff. 16 Q. Referring to Exhibit No. 2 that's in front of 17 you, do -- is that similar to the printout that I might 18 see for a -- for the current records on a donor who's 19 currently donating, in the sense -- what I mean is, do 20 you still keep medical notes that can be printed out on a 21 sheet like that? 22 A. I'm trying to understand the question, I guess. 23 Are you asking, can I print this out for any donor -- 24 Q. Yes. 25 A. -- medical notes? Yes.</p>

Sam Schultz  
April 10, 2017

58 to 61

<p style="text-align: right;">Page 58</p> <p>1 A. They should not be in the production areas.</p> <p>2 Q. And if -- is the production area where the</p> <p>3 actual plasma is withdrawn?</p> <p>4 A. It's the processing areas.</p> <p>5 Q. So does that mean the plasma has already been</p> <p>6 withdrawn and it is taken to the production area?</p> <p>7 A. That would be in like the screening booth where</p> <p>8 they ask the questions or -- yes, on the donor floor as</p> <p>9 well.</p> <p>10 Q. Okay. All that would be considered the --</p> <p>11 A. Production area.</p> <p>12 Q. -- production? All right. Are there occasions</p> <p>13 where you or other CSL staff will ask for a doctor's note</p> <p>14 from the donor about something to confirm whether the</p> <p>15 donation can go forward?</p> <p>16 A. Yes.</p> <p>17 Q. Give me an example of when that might happen.</p> <p>18 A. If they come in and say they have conditions,</p> <p>19 but they can't remember what they are or what the</p> <p>20 medications are. Or I know I take five medications, but</p> <p>21 I don't know what they are, things like that, that we</p> <p>22 need additional follow-up to -- to reference.</p> <p>23 Q. All right. I think you -- if -- if I'm</p> <p>24 remembering correctly, you told me about two sort of</p> <p>25 nationwide databases that you have access to. One is a</p>	<p style="text-align: right;">Page 59</p> <p>1 list of donations that the person might have made.</p> <p>2 And the other is whether they're on a</p> <p>3 deferral list for some viral marker. Is that -- am I</p> <p>4 remembering right?</p> <p>5 A. Somewhat. It's not necessarily a list. I</p> <p>6 don't get to see donations. I don't get to see -- other</p> <p>7 than the donation that would affect the suitability for</p> <p>8 today, meaning the two days in a row or the two in seven.</p> <p>9 It -- it pops up. That's all it's going</p> <p>10 to be. It might be one or two. I don't know where it</p> <p>11 was made, what company. It just says there's two in the</p> <p>12 last seven days. They're not acceptable. I don't have</p> <p>13 any other information on that --</p> <p>14 Q. Under-</p> <p>15 A. -- on the ND. I don't -- they're either a</p> <p>16 match or not a match.</p> <p>17 Q. Understood. Is there any national database for</p> <p>18 people who are deferred for reasons other than a viral</p> <p>19 marker, that you're aware of?</p> <p>20 A. No.</p> <p>21 Q. Is there any other way in which you could</p> <p>22 determine whether someone has a deferral somewhere else?</p> <p>23 A. You can ask them.</p> <p>24 Q. Anything else?</p> <p>25 A. Not generally, no.</p>
<p style="text-align: right;">Page 60</p> <p>1 Q. Are there any SOPs that relate to misconduct or</p> <p>2 threats by donors?</p> <p>3 A. I believe so, yes.</p> <p>4 Q. Do you recall generally what they say or what</p> <p>5 the point of them is?</p> <p>6 A. I do not.</p> <p>7 Q. Are there any SOPs that relate to the physical</p> <p>8 ability of a donor in the sense of their ability to walk,</p> <p>9 transfer, get on the scale, etc.? Any SOPs that relate</p> <p>10 to that?</p> <p>11 A. Aside from this one that we reviewed?</p> <p>12 Q. Right, aside from Exhibit No. 4 that we looked</p> <p>13 at.</p> <p>14 A. There is another one regarding impaired donors.</p> <p>15 Q. Okay. So just for the record, you were looking</p> <p>16 at Exhibit No. 4, which the title is given, Medical Staff</p> <p>17 Reference -- Conditions Guideline. We've already talked</p> <p>18 about this. And you were looking on page 255 of it.</p> <p>19 And in the right-hand column, you were</p> <p>20 pointing out the bold type there reflecting impaired</p> <p>21 donors and some other things. But that's what you were</p> <p>22 talking about?</p> <p>23 A. Yes.</p> <p>24 Q. And you also were looking at -- in the top left</p> <p>25 corner, it says disabilities, dash, see SOP for specific</p>	<p style="text-align: right;">Page 61</p> <p>1 guidance. Do you understand that reference to an SOP to</p> <p>2 be talking about these same things that are in bold?</p> <p>3 A. Yes.</p> <p>4 Q. Might there be other SOPs that give specific</p> <p>5 guidance other than those ones listed there, or would</p> <p>6 that be it?</p> <p>7 A. There might be.</p> <p>8 Q. How would you find them?</p> <p>9 A. Occasionally they're listed as you go through</p> <p>10 some of the other SOPs that are cross-referenced.</p> <p>11 Q. If -- if you are wondering whether there's an</p> <p>12 SOP on specific guidance related to one of the things</p> <p>13 listed here and it -- you're worried that perhaps these</p> <p>14 bolded items may not address what you're talking about in</p> <p>15 particular, how do you go about looking for something?</p> <p>16 A. I can search on my computer.</p> <p>17 Q. And how do you do that? Like, what do you</p> <p>18 search?</p> <p>19 A. The list of our SOPs.</p> <p>20 Q. And do you do a word search, or do you read</p> <p>21 down the page, or how would you do that?</p> <p>22 A. Both.</p> <p>23 Q. And is the -- if you're doing a word search, is</p> <p>24 the search being made of the SOP title or is it also</p> <p>25 searching the text of the SOP?</p>

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Page 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
CORPUS CHRISTI DIVISION

MARK SILGUERO,

Plaintiff,

v.

CSL PLASMA INC.,

Defendant.

§  
§  
§  
§  
§  
§  
§  
§

CIVIL ACTION  
NO. 2:16-CV-00361

\*\*\*\*\*

ORAL DEPOSITION OF

MARK SILGUERO

April 10, 2017

\*\*\*\*\*

ORAL DEPOSITION OF MARK SILGUERO, produced as a  
witness at the instance of the Defendant, and duly sworn,  
was taken in the above-styled and numbered cause on the  
10th of April 2017, from 8:25 a.m. to 10:15 a.m., before  
Isabel Connor, CSR in and for the State of Texas,  
reported by machine shorthand, at the offices of U.S.  
Legal Support, 802 North Carancahua Street, Suite 2280,  
Corpus Christi, Texas, pursuant to the Federal Rules of  
Civil Procedure.

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10 to 13

<p style="text-align: right;">Page 10</p> <p>1 A. All kinds. I mean, all kinds. Literally all 2 kinds. Construction, retail, selling funeral property, 3 little bit of everything. 4 Q. So when did you get your RN license? 5 A. Began the RN program in 2007 and ended 2009 -- 6 I finished. 7 Q. Have you ever served in the military? 8 A. No, ma'am. 9 Q. Are you currently employed? 10 A. No, ma'am. 11 Q. When was your last job? 12 A. August of 2014. 13 Q. And what were you doing at that time? 14 A. I was the director of nurses at a detention 15 center. 16 Q. Do you consider yourself retired, or are you 17 still looking for work? 18 A. Disabled. 19 Q. So do you get some kind of income from the 20 government or state? 21 A. Yes, disability. 22 Q. And how long have you gotten disability? 23 A. It began in February of 2015, I believe. 24 Q. When did you first donate plasma, if you 25 remember?</p>	<p style="text-align: right;">Page 11</p> <p>1 A. I don't remember. Back in my 20s. 2 Q. And how did you hear about donating plasma? 3 A. Friend at the time. 4 Q. Where -- do you remember where you went back in 5 your 20s to donate? 6 A. The name of the company was -- the initials are 7 NABI. That's all I remember. 8 Q. Do you know how often you went back then? 9 A. Probably like, off and on, a good two years. 10 Was during college, some classes. 11 Q. And why did you donate back then? 12 A. Just supplement. Was going to school. 13 Q. And why did you stop donating at that time? 14 A. I received employment. I would go 15 occasionally, you know, just still -- 16 Q. So after your 20s, when was the next time that 17 you donated plasma? 18 A. I've been going off and on right -- since my 19 20s up until -- well, you know, till I -- I had surgery, 20 so that disqualified me from donating for a while. So, 21 you know, it's, like I said, off and on since my 20s. 22 Q. And what was the reason for donating plasma off 23 and on? 24 A. Just, you know, the money to -- you know, from 25 the donation, of course, was helpful. You know, just --</p>
<p style="text-align: right;">Page 12</p> <p>1 you know, just kind of felt like it was helping out 2 somehow. 3 Q. So since you've donated at CLS, you said you've 4 donated more recently. Where are you donating in the 5 past couple of years? 6 A. Well, I was donating at CSL. After that -- 7 there's a nearby donation place called Trifolos 8 (phonetic) or something like that. That's the name of 9 the company, Trifolos, Trifol, something like that. 10 Q. And how often did you donate there? 11 A. Pretty routinely, every -- you know, twice a 12 week is what you're allowed to do, so -- probably year 13 and a half, two years, I think, something like that. 14 Q. Did you start going there immediately after you 15 stopped going to CSL? 16 A. Not -- yeah, not too soon after. Not too soon 17 after. 18 Q. And when was your most recent donation? 19 A. It would have been in January prior to my 20 surgery. 21 Q. And you said you're disqualified now because of 22 the surgery. Is that right? 23 A. Yeah. Right. There's, you know, certain 24 requirements and -- due to my surgery, I have to wait, I 25 think, a year before I'm able to donate again.</p>	<p style="text-align: right;">Page 13</p> <p>1 Q. Do you know why that is? 2 A. Not sure. I imagine has to do with the 3 hardware, new hardware in my body, or my knee, you know, 4 just something foreign in there. 5 Q. Okay. So let's talk about your knees. When 6 did they start hurting you, bothering you? Did you have 7 an injury? What kind of caused all this to start? 8 A. Yeah. Well, back in '87, '88, I had a total 9 new reconstruction of my left knee. Consequently 10 throughout the years -- I'm 50 now. This was when I was 11 about 20. I've had to compensate with my right leg, 12 which put a lot of wear and tear on it. 13 Degenerative joint disease is like one of 14 the things going on with both knees. Had this one scoped 15 out in 2006, my right one, because of the fact that I 16 worked at a magazine route company. And due to an injury 17 there, they had to scope out my knee. 18 It just kind of weakened it. Again, the 19 compensation -- because of the weakness of the -- of the 20 other one, just wore it out to -- to the point I had to 21 have it replaced January 2017. 22 Q. So were there any other surgeries besides the 23 one in 1987 and then the one in 2017? 24 A. Yes, in 2006. They -- arthroscopic surgery of 25 my right knee.</p>



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14 to 17

<p style="text-align: right;">Page 14</p> <p>1 Q. Any other surgeries on your knees besides those 2 three? 3 A. I had a reconstruction, arthroscopic. I think 4 that's -- surgeries -- as far as surgeries, yeah, that's 5 it. That's enough. 6 Q. That is plenty. So how has the issues with 7 your knees impacted your walking over the years? 8 A. Initially, not too -- too much. I was younger 9 and stronger. As I got a little older and after my 10 injury in 2006, I could handle -- it limit me somewhat. 11 It did limit me somewhat, but still carried on my jobs 12 and stuff, you know, pretty much. 13 2000 -- after I had it scoped out in 2006, 14 it -- well, went through the nursing program in 2007. 15 Generally, it's just -- made it a little -- my right knee 16 and my left knee is just weaker throughout the years. I 17 guess say that. 18 Q. Why did you stop working at the detention 19 center? 20 A. Due to my -- my knees. It just -- it was too 21 painful. Part of the requirements working there is to 22 respond to an emergency within four minutes, and I was no 23 longer able to meet that time limit. 24 Q. And when in 2014 did you stop working? Do you 25 remember --</p>	<p style="text-align: right;">Page 15</p> <p>1 A. August. 2 Q. -- what month? 3 A. August. 4 Q. So is it fair to say that up until August 2014, 5 your knees were bad but not bad enough to prevent you 6 from working, and then after that, they did prevent you 7 from working? 8 A. Say that again. I'm sorry. 9 Q. I guess what made you decide in August 2014 to 10 stop working? Did they get worse that month? Was it 11 just kind of a buildup? What happened? 12 A. It -- because of not being able to meet my job 13 requirements. You know, it just kind of led to, you 14 know, limited options where I could work. So, yeah, I 15 had to stop work. 16 Q. Were your knees worse in August of 2014 than 17 they were in August of 2013? 18 A. Oh, yeah. Right. 19 Q. Okay. Did anything happen to make them worse 20 around the August 2014 time or -- that you remember? 21 A. Just, I mean, years of wear and tear just 22 caught up with it, August -- 23 Q. How long have you used a cane to walk? 24 A. Started around Houston, I believe. Probably 25 around 2013, as far -- probably -- I don't know. I don't</p>
<p style="text-align: right;">Page 16</p> <p>1 know. Maybe August, September, somewhere around there, 2 that time, of 2013. I was working in Houston at another 3 detention center in -- yeah, more or less that time. 4 Q. Was there anything specific between, say, 5 August '13 and August 2014 that made your knees worse or 6 just the general deterioration? 7 A. I imagine the general deterioration. 8 Q. I believe we have records that say around 9 July 2013 you visited a doctor to start talking about a 10 knee replacement. Does that sound right? 11 A. Uh-huh. Yes, ma'am. 12 Q. But you didn't get a knee replacement at that 13 point, correct? 14 A. Right. Right. 15 Q. Why did you not get one at that point? 16 A. My surgeon felt I needed to lose weight and, 17 you know, be safer. 18 Q. Okay. So what did you do for a treatment plan 19 for your knees between 2013 and then 2017 when you 20 finally did get the replacement? 21 A. Diet and exercise. 22 Q. Did your knees continue to get worse during 23 that time? 24 A. I guess they were pretty much the same. I 25 mean, just -- they were real bad already. So imagine it</p>	<p style="text-align: right;">Page 17</p> <p>1 just -- just kind of the same. I mean, I already needed 2 the replacement. So I imagine they were just pretty 3 much, you know, getting worse as time progressed. 4 Q. So why did you eventually get the surgery in 5 2017? 6 A. I mean, obviously, I was in pain and needed 7 that done. I mean, also just, you know, future -- hoping 8 to improve my health. 9 Q. Would it be fair to say from 2013, when you 10 went to talk to your doctor, that you were always 11 planning on having the surgery? 12 A. Having -- replacement? 13 Q. Yes. 14 A. I was hoping it wouldn't be. But, yeah, I 15 mean, I kind of knew already, as a nurse, that was my 16 next option probably. 17 Q. Did you think maybe with diet and exercise, 18 your knee would be okay enough that you wouldn't have to 19 have surgery? 20 A. I would -- I did hope there would be some 21 improvement, yeah. I mean, surgery is not like my most 22 favorite thing to do. 23 Q. So what exactly prompted the surgery in 2017? 24 Were you finally at the weight you needed to be at? 25 A. Right.</p>

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18 to 21

<p style="text-align: right;">Page 18</p> <p>1 Q. Did it hurt too much or --</p> <p>2 A. Right. I lost significant amount of weight to</p> <p>3 qualify.</p> <p>4 Q. And you have another surgery scheduled; is that</p> <p>5 right?</p> <p>6 A. Yes, ma'am.</p> <p>7 Q. And when is that?</p> <p>8 A. April 17th.</p> <p>9 Q. Coming up.</p> <p>10 A. Yes, ma'am.</p> <p>11 Q. So what knee did you have surgery on in</p> <p>12 January?</p> <p>13 A. The right knee.</p> <p>14 Q. And then you're having surgery on the left</p> <p>15 knee next?</p> <p>16 A. Yes, ma'am.</p> <p>17 Q. And then, hopefully, no more surgeries after</p> <p>18 that?</p> <p>19 A. Hopefully.</p> <p>20 Q. So you understand you're bringing a disability</p> <p>21 discrimination claim, right?</p> <p>22 A. Yes, ma'am.</p> <p>23 Q. So is the problems with your knee? Is that</p> <p>24 what you consider to be your disability, then?</p> <p>25 A. Right. Yes, ma'am.</p>	<p style="text-align: right;">Page 19</p> <p>1 Q. Anything else that you consider to be a</p> <p>2 disability for this lawsuit?</p> <p>3 A. No, ma'am.</p> <p>4 Q. So this lawsuit is based on an event in 2000 --</p> <p>5 early 2015. Do you remember the condition of your knees</p> <p>6 around that time?</p> <p>7 A. They were in bad shape. Needed to be replaced.</p> <p>8 Q. Were you in any physical therapy on your knees</p> <p>9 between the 2013, 2017 time period?</p> <p>10 A. Just occasional swimming, things like that.</p> <p>11 Q. Do you remember when you first went to CSL</p> <p>12 Plasma?</p> <p>13 A. I don't remember when I first went, no, ma'am.</p> <p>14 (Silguero Exhibit No. 1 marked.)</p> <p>15 Q. (By Ms. Willing) So I'm handing you what's</p> <p>16 been marked as Exhibit No. 1.</p> <p>17 A. I look better with hair on me, my face.</p> <p>18 Q. I'm not sure exactly when this picture is from.</p> <p>19 But I doubt it's the most flattering camera that they</p> <p>20 use. Kind of like driver's license pictures,</p> <p>21 unfortunately.</p> <p>22 A. Uh-huh.</p> <p>23 Q. So this is a printout of your donor file from</p> <p>24 CSL. If you look at the bottom left corner where the</p> <p>25 printing is, it indicates you came in at least once in</p>
<p style="text-align: right;">Page 20</p> <p>1 December 16, 2011. Do you remember that?</p> <p>2 A. I don't remember that, but I imagine it's true.</p> <p>3 Q. You don't have any reason to believe it's not</p> <p>4 true?</p> <p>5 A. Right.</p> <p>6 Q. And then if you look, it shows the next time --</p> <p>7 it has you coming in as January 12, 2014. Do you see</p> <p>8 that?</p> <p>9 A. Uh-huh. Yes, ma'am.</p> <p>10 Q. Do you have any recollection of why you would</p> <p>11 have waited three -- I guess really two years to --</p> <p>12 between visits?</p> <p>13 A. I was living in Houston.</p> <p>14 Q. Oh, okay. So you were donating in Houston</p> <p>15 during the 2012, 2013 --</p> <p>16 A. I was employed also as an RN.</p> <p>17 Q. So when did you come back to Corpus Christi?</p> <p>18 A. 2014.</p> <p>19 THE WITNESS: Was it January 2014?</p> <p>20 A. I believe it was January 2014.</p> <p>21 Q. (By Ms. Willing) Okay. And so what years did</p> <p>22 you live in Houston?</p> <p>23 A. Believe it's like December, November of 2011.</p> <p>24 THE WITNESS: Right?</p> <p>25 A. And then came back around, oh, gosh, May of --</p>	<p style="text-align: right;">Page 21</p> <p>1 THE WITNESS: 2013?</p> <p>2 A. 2013, I think. Yeah, 2013. Yeah, I'm actually</p> <p>3 right.</p> <p>4 Q. (By Ms. Willing) So did you donate plasma</p> <p>5 while you were in Houston?</p> <p>6 A. No, ma'am. I was employed. I did try. It was</p> <p>7 just the -- I did at one time attempt to. It's just I</p> <p>8 hadn't moved my -- changed my driver's license and all</p> <p>9 that and didn't want to deal with it. Their driver's</p> <p>10 license office is over there.</p> <p>11 Q. So do you remember why you started donating in</p> <p>12 January of 2014?</p> <p>13 A. I imagine probably needed some cash.</p> <p>14 Q. You were still working at that time, right?</p> <p>15 A. No, ma'am. I had just moved back from Houston.</p> <p>16 2014?</p> <p>17 Q. Believe you were --</p> <p>18 A. I was --</p> <p>19 Q. -- you said earlier you worked in 2014?</p> <p>20 A. I'm not exactly sure. January 2014, right?</p> <p>21 That's what you're looking at?</p> <p>22 Q. Yeah.</p> <p>23 A. Oh, yeah. Yeah, yeah. I'm sorry. I guess I</p> <p>24 wasn't working at the time. I imagine that's why.</p> <p>25 Q. So you said your last job was at the detention</p>

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22 to 25

<p style="text-align: right;">Page 22</p> <p>1 center; is that right?</p> <p>2 A. Yeah. Yes, ma'am.</p> <p>3 Q. And so --</p> <p>4 THE WITNESS: Was it 2014? Right? 2013?</p> <p>5 A. Oh, I'm sorry. It was August 2013, I stopped</p> <p>6 working at the detention center. I'm terrible with dates</p> <p>7 and stuff.</p> <p>8 Q. (By Ms. Willing) That's okay. It's been a few</p> <p>9 years. It's hard to remember. I'm trying to get a</p> <p>10 sense, given what we know.</p> <p>11 A. I understand.</p> <p>12 Q. Okay. And so these dates on Exhibit 1 show</p> <p>13 that you came in a few times between January 2014 and</p> <p>14 April 2014. You see that?</p> <p>15 A. Yes. Yes, ma'am.</p> <p>16 Q. Do you remember coming in that time or those</p> <p>17 times?</p> <p>18 A. Sure. Sure, sure, sure. I do -- yeah. I</p> <p>19 mean, I do remember donating there, yes. Uh-huh.</p> <p>20 (Silguero Exhibit No. 2 marked.)</p> <p>21 Q. (By Ms. Willing) Handing you what's been</p> <p>22 marked as Exhibit 2. So these are medical notes from CSL</p> <p>23 Plasma's file.</p> <p>24 A. Sure.</p> <p>25 Q. So all -- they go reverse chronological, I</p>	<p style="text-align: right;">Page 23</p> <p>1 guess. So the ones on the bottom are from 2014, and they</p> <p>2 go back up to 2015.</p> <p>3 A. Oh, these are notes. Okay.</p> <p>4 Q. Yeah. So it's a little bit more explanation.</p> <p>5 A. As far as dates is what I'm looking at.</p> <p>6 Q. Yeah. The dates on the right side are -- the</p> <p>7 date stamp is not correct, but there's dates within the</p> <p>8 notes. So if you look at -- on the column that says</p> <p>9 donor medical SEQ. And then there's numbers under that.</p> <p>10 A. Yes, ma'am.</p> <p>11 Q. Those are basically line numbers. That's</p> <p>12 probably the easiest way to refer to these notes. If you</p> <p>13 look at line 12, it says review of MQ medical approvals</p> <p>14 complete.</p> <p>15 And then line 13 says donor uses cane for</p> <p>16 support. So do you remember having to get approval to</p> <p>17 donate back in January 2014?</p> <p>18 A. No.</p> <p>19 Q. That's just fine. And then starting line 10,</p> <p>20 it says donor has less than three-inch bruise --</p> <p>21 A. Yes.</p> <p>22 Q. -- not okay to donate --</p> <p>23 A. Yeah.</p> <p>24 Q. -- until resolved. Do you remember that?</p> <p>25 A. Yes. Yes. Yes. They had, I guess -- when</p>
<p style="text-align: right;">Page 24</p> <p>1 they went to draw -- or stick me, they kind of, you know,</p> <p>2 went through the vein. Caused real bad bruising.</p> <p>3 Q. And so did they tell you that you couldn't</p> <p>4 donate at that time?</p> <p>5 A. Right, till it healed up.</p> <p>6 Q. So they told you not to come back until the</p> <p>7 bruised had healed; is that correct?</p> <p>8 A. Right. But this was not on 1/20 -- oh, wait.</p> <p>9 '14, yeah. Okay. Never mind. Yeah. The dates are</p> <p>10 what -- all right.</p> <p>11 Q. So that was on January 12th. And then it looks</p> <p>12 like you came back January -- or no. That was --</p> <p>13 sorry -- January 15th. Then you came back January 20th,</p> <p>14 and you still had bruising.</p> <p>15 A. Uh-huh.</p> <p>16 Q. And so you couldn't donate; is that right?</p> <p>17 A. Correct.</p> <p>18 Q. And then, finally, on January 22nd, the bruise</p> <p>19 had healed, and you could donate. You see that?</p> <p>20 A. Yes. Yes. Yes. I see.</p> <p>21 Q. So do you remember if this was something that</p> <p>22 happened often that you would go in and they would tell</p> <p>23 you --</p> <p>24 A. No. It was just, I believe, onetime incident</p> <p>25 that I remember. You know, they just, you know, stuck me</p>	<p style="text-align: right;">Page 25</p> <p>1 wrong and caused bruising. And had to wait till that</p> <p>2 cleared up. Yeah, I remember.</p> <p>3 Q. Do you remember any other times that you went</p> <p>4 in and you didn't get to donate for any reason? Not the</p> <p>5 one -- the main one that we're talking about in January</p> <p>6 2015, but at CSL or other places where you couldn't</p> <p>7 donate for a few days, something like this?</p> <p>8 A. Yeah. Yeah.</p> <p>9 Q. What kind of things were those?</p> <p>10 A. Well, I mean, it wasn't necessarily where my</p> <p>11 blood -- but I did get to donate. My blood pressure was</p> <p>12 a little high. Told me to go sit down for a minute and,</p> <p>13 you know, went back, checked it. Everything was fine.</p> <p>14 Q. Do you remember any other times like this where</p> <p>15 you had to come back, say, a couple days later?</p> <p>16 A. Well, where I currently donate, yeah, because</p> <p>17 my plasma, I guess, was a little too -- hyperlipidemia,</p> <p>18 which, you know, I had to drink water and just resolve it</p> <p>19 in a day. It was just -- but, yeah.</p> <p>20 Q. So they told you you couldn't donate that day,</p> <p>21 but to come back, say, the next day and see if you could</p> <p>22 donate again?</p> <p>23 A. Yeah. That's normal. It happens all the time,</p> <p>24 not just myself.</p> <p>25 Q. Do you remember why you stopped donating in</p>

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26 to 29

<p style="text-align: right;">Page 26</p> <p>1 April 2014?</p> <p>2 A. April. I don't remember, no.</p> <p>3 Q. You said at one point you had high blood</p> <p>4 pressure when you went in to donate. Did you get to</p> <p>5 donate that day, or did you --</p> <p>6 A. Yes.</p> <p>7 Q. -- have to come back another day?</p> <p>8 A. No. I got to donate that day.</p> <p>9 Q. So why don't you walk us through a little bit</p> <p>10 about how the donation generally goes when you go to a</p> <p>11 plasma center. What happens when you first walk in the</p> <p>12 door?</p> <p>13 A. Well, if it's a routine donation, what you do</p> <p>14 is sign in. And where I -- where I donate, you just sit</p> <p>15 down -- sit down till you're called, go into a kiosk,</p> <p>16 answer the questions, get a little band stating you did</p> <p>17 that.</p> <p>18 Wait for your name to be called, which</p> <p>19 leads you to the screening room where they take your</p> <p>20 blood pressure, temperature, get a little blood sample,</p> <p>21 weigh you, and evaluate your blood as far as</p> <p>22 hyperlipidemia or your medical levels.</p> <p>23 Q. So is that every time that they do that</p> <p>24 evaluation?</p> <p>25 A. That's in a routine donation. And after -- if</p>	<p style="text-align: right;">Page 27</p> <p>1 you're accepted, you wait a few hours -- I'm sorry.</p> <p>2 Wait -- seems like a few hours. You wait a little while.</p> <p>3 They call you to a back room where they'll, you know,</p> <p>4 hook you up to a plasma machine, basically, and you give</p> <p>5 your donation.</p> <p>6 Q. And the first time you go somewhere new, is</p> <p>7 there additional screening?</p> <p>8 A. Right. Yes, ma'am.</p> <p>9 Q. What kind of -- do you know -- remember what</p> <p>10 kind of questions they asked?</p> <p>11 A. There's paperwork proving your residency and</p> <p>12 who you are. There's also paperwork for the facility,</p> <p>13 physical. And other than screening, of course, an</p> <p>14 explanation of the whole process also.</p> <p>15 Q. So do you have friends and -- or relatives that</p> <p>16 currently donate plasma?</p> <p>17 A. Currently, no.</p> <p>18 Q. But you said you first heard from a friend. So</p> <p>19 at one point you knew people that were donating; is that</p> <p>20 right?</p> <p>21 A. Yeah. Yes. Yes.</p> <p>22 Q. You mentioned that short deferrals for little</p> <p>23 things were normal. Did you have friends that got</p> <p>24 deferred for a couple days for little things here and</p> <p>25 there?</p>
<p style="text-align: right;">Page 28</p> <p>1 A. No. But you -- it's pretty much given. You go</p> <p>2 into be screened. If you don't wait and -- sit down and</p> <p>3 be called to the back, you leave right away. And that's</p> <p>4 just a clear indication you weren't accepted, yeah, for</p> <p>5 whatever reason, you know.</p> <p>6 Q. So within your experience at plasma centers,</p> <p>7 you know that people walk in, and sometimes they get</p> <p>8 deferred, and they don't get to donate?</p> <p>9 A. Right. Yeah.</p> <p>10 Q. And if I use the word deferred, have you heard</p> <p>11 that before?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. And that means that you don't get to</p> <p>14 donate plasma?</p> <p>15 A. There's two types. There's permanent and</p> <p>16 temporary deferral.</p> <p>17 Q. And what's the difference?</p> <p>18 A. Pretty much one is on a temporary basis. The</p> <p>19 other one is permanent.</p> <p>20 Q. So you know that not everyone who wants to</p> <p>21 donate plasma gets to donate plasma, right?</p> <p>22 A. Yes, I understand that.</p> <p>23 Q. And do you know some of the reasons that those</p> <p>24 people get deferred?</p> <p>25 A. Yes. Diseases, stuff like that, I imagine.</p>	<p style="text-align: right;">Page 29</p> <p>1 Q. And even people that are generally qualified to</p> <p>2 donate plasma, there may be days where they can't donate</p> <p>3 and get temporarily deferred; is that right?</p> <p>4 A. Sure.</p> <p>5 Q. You said that's normal?</p> <p>6 A. From what I've seen, yeah.</p> <p>7 Q. When you go for a routine donation, about how</p> <p>8 long are you at the plasma center?</p> <p>9 A. Routine -- probably around two hours, two and a</p> <p>10 half.</p> <p>11 Q. Do you know how many places there are to donate</p> <p>12 plasma in Corpus Christi?</p> <p>13 A. I think there's two.</p> <p>14 Q. You said two?</p> <p>15 A. I believe there's two. I'm not a hundred</p> <p>16 percent on that.</p> <p>17 Q. So would that be CSL and then the place that</p> <p>18 you're donating now?</p> <p>19 A. Yeah. Those are the only two I'm aware of.</p> <p>20 Q. So when you go to CSL to donate plasma, it was</p> <p>21 just the screening and the donation, and then you left;</p> <p>22 is that correct?</p> <p>23 A. Screening, on a routine donation, yeah.</p> <p>24 Q. Did you ever buy anything when you were there?</p> <p>25 A. Buy anything? Coke.</p>

Mark Silguero  
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34 to 37

<p style="text-align: right;">Page 34</p> <p>1 they told you that you were temporarily -- temporarily 2 deferred for the bruising? 3 A. No, ma'am. 4 Q. And then you mentioned a time that you couldn't 5 donate for a short period, not a whole day, but for a 6 couple hours, because you had high blood pressure? 7 A. Right. 8 Q. Do you know why you couldn't donate when you 9 have high blood pressure? 10 A. Imagine it's unsafe for the patient or the 11 client or whatever. 12 Q. And by the client you mean you? 13 A. Right. 14 Q. So it's your understanding that sometimes you 15 can't donate because it's unsafe for you to donate; is 16 that right? 17 A. If you don't fall within their parameters. 18 Q. And so some of those parameters are to make 19 sure that the patient -- the person that's donating is 20 safe, correct? 21 A. I imagine so, yes. 22 Q. So as a nurse does it make sense to you that 23 someone who had an injury, who needed their plasma to 24 heal, would not be able to donate? 25 A. You're asking me to think for them. You know,</p>	<p style="text-align: right;">Page 35</p> <p>1 I don't know how their job is -- what their job 2 requirements are, what they're trained. I don't know. 3 Q. Well, you told me that plasma is used for 4 healing; is that correct? 5 A. Right. Right. 6 Q. So given your understanding of that, would it 7 make sense to you that someone who was injured and so 8 needed to heal would then need their plasma and could not 9 donate? 10 A. I don't -- I don't know all their parameters. 11 I don't know all their medical requirements. I don't 12 know their policies and procedures. I don't know. 13 Q. I'm not asking about the policies. I'm just 14 asking if it makes -- 15 A. Right. 16 Q. -- sense to you or not. 17 A. But, I mean, their training -- I don't know. 18 The answer is I don't know. 19 Q. When they told you you couldn't donate because 20 of high blood pressure, did you think that was 21 discriminatory? 22 A. No, ma'am. 23 Q. Have you ever been temporarily deferred by any 24 plasma center for any other reason? 25 A. Yes.</p>
<p style="text-align: right;">Page 36</p> <p>1 Q. What were those? 2 A. Hyperlipidemia. 3 Q. And what is hyperlipidemia? 4 A. It's when your cholesterol is too high and 5 interferes with the plasma, therefore contaminating it. 6 It's not useful to the plasma center. 7 Q. And was that at CSL, or was that somewhere 8 else? 9 A. Somewhere else. 10 Q. Did you think it was discriminatory when you 11 were temporarily -- temporarily deferred for 12 hyperlipidemia? 13 A. No, ma'am. 14 Q. So would you agree that CSL has the right to 15 defer people if their plasma is going to contaminate the 16 plasma supply? 17 A. Sure. 18 Q. Would you agree that CSL has the right to defer 19 someone if donating plasma is going to be unsafe for that 20 person? 21 A. Yes. 22 Q. Okay. Let's talk about your visit to CSL on 23 January -- I believe it was January 2nd, 2015. 24 A. Uh-huh. 25 Q. Does that date sound right to you?</p>	<p style="text-align: right;">Page 37</p> <p>1 A. Yes. Well, yeah. 2 Q. Did anyone come with you that day? 3 A. Yes. 4 Q. Who? 5 A. Would have been my wife and my stepdaughter. 6 Q. Were they also donating plasma? 7 A. Yes, ma'am. 8 Q. Do you remember if they did donate plasma that 9 day? 10 A. They -- they both did. 11 Q. And what's your stepdaughter's name? 12 A. Ashley. 13 Q. Were Lisa and Ashley regular donors? 14 A. Lisa had been. 15 Q. What about Ashley? 16 A. I don't believe so. 17 Q. Was that her first time? 18 A. Yes. 19 Q. So it looks like, from our records, that you 20 had not been to CSL since April. So that would have been 21 like eight months or so before? 22 A. Right. 23 Q. So did you have to do -- go through the whole 24 new donor process when you got there in 2015? 25 A. Right.</p>



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38 to 41

<p style="text-align: right;">Page 38</p> <p>1 Q. So do you remember what happened when you 2 initially got to CSL in 2015?</p> <p>3 A. Signed in, showed the person at the desk my 4 paperwork. I received a booklet to read through. Saw a 5 video, if I'm not mistaken, and was waiting to either get 6 screened or do my physical.</p> <p>7 Q. Do you remember what was in the booklet that 8 you read through?</p> <p>9 A. Some.</p> <p>10 Q. Sorry. What was that?</p> <p>11 A. Some. I remember some of what's in the book.</p> <p>12 Q. Oh. What do you remember?</p> <p>13 A. Some of the reasons why you couldn't donate, 14 things like that, how to, you know, prepare for your 15 donation as far as healthwise, things of that nature.</p> <p>16 Q. And do you remember what was in the -- on the 17 video?</p> <p>18 A. Yes.</p> <p>19 Q. What was that?</p> <p>20 A. Also as -- how plasma is used and, you know, 21 what they do with your donation.</p> <p>22 Q. Okay. So after you got the booklet and saw the 23 video, then what happened?</p> <p>24 A. I was asked to sit in the back till it was my 25 turn to either, again, be given a physical or screen.</p>	<p style="text-align: right;">Page 39</p> <p>1 Q. So you were sitting in like the lobby area or 2 somewhere else?</p> <p>3 A. I guess it would be lobby area in the back area 4 of where they do all that stuff.</p> <p>5 Q. Okay. And then what happened?</p> <p>6 A. I was called into the screening room. I walked 7 in, put my cane down, stepped up to the chair. She told 8 me I couldn't donate because I couldn't transfer, because 9 of my gait and because of my cane, I believe.</p> <p>10 Q. So because of your gait. What did she say 11 about that?</p> <p>12 A. Basically -- I know it was something concerning 13 my cane, you know, because I use a cane. I couldn't 14 transfer, you know, which, you know, I hadn't even been 15 given the opportunity to show her I could or couldn't, 16 you know.</p> <p>17 Q. Do you remember if you were walking with a limp 18 that day?</p> <p>19 A. Not with my cane, if I had my cane.</p> <p>20 Q. Did she tell you anything else?</p> <p>21 A. That was pretty much it.</p> <p>22 Q. And what did you say in response?</p> <p>23 A. You know, obviously upset me. I just -- you 24 know, I knew I was being discriminated against and, you 25 know, told her -- you know, shook my finger and said, you</p>
<p style="text-align: right;">Page 40</p> <p>1 know, you're going to be sorry.</p> <p>2 Q. So you shook your finger and told her she would 3 be sorry?</p> <p>4 A. Yes.</p> <p>5 Q. What did you mean by that?</p> <p>6 A. Meant I was going to call her supervisor or -- 7 or corporate, take, you know, some kind of correction 8 action, you know, or legal action.</p> <p>9 Q. Did you say anything else?</p> <p>10 A. No, ma'am.</p> <p>11 Q. Did you raise your voice?</p> <p>12 A. Probably no louder than I'm speaking right now.</p> <p>13 Q. Did she explain any more about why she was 14 deferring you?</p> <p>15 A. No.</p> <p>16 Q. Did she say how long the deferral would be?</p> <p>17 A. No.</p> <p>18 Q. How long did you understand it would be?</p> <p>19 A. Permanent, because, I mean, I was -- she's 20 basing it on my gait and my transfer. I mean, that's -- 21 that wasn't going to change overnight.</p> <p>22 Q. Did she tell you it was going to be permanent?</p> <p>23 A. And I'd been there prior plenty times before.</p> <p>24 Q. Did she say it was going to be a permanent 25 deferral?</p>	<p style="text-align: right;">Page 41</p> <p>1 A. I understood it to be.</p> <p>2 Q. But did she say it was going to be a permanent 3 deferral?</p> <p>4 A. I don't remember. She just said, you're 5 deferred. You know, going to defer you. Can't transfer.</p> <p>6 Q. So at that time you were planning to get knee 7 replacement surgery, right?</p> <p>8 A. No. I was in the process of losing weight. I 9 had already -- you know, they told me, you need to lose 10 weight and diet before we do that.</p> <p>11 Q. But you were losing weight so that you could 12 get the knee replacement surgery, right?</p> <p>13 A. Trying to, yeah.</p> <p>14 Q. So did you think that once you got the knee 15 replacement surgery, then you could go back and donate?</p> <p>16 A. Sure. That or work, something.</p> <p>17 Q. So, then, it wouldn't be a permanent deferral, 18 right?</p> <p>19 A. Say that again.</p> <p>20 Q. So you said you understood it to be a permanent 21 deferral because your gait was not going to improve. Is 22 that correct?</p> <p>23 A. I mean, she just said you're deferred, okay?</p> <p>24 You're asking me to guess what she meant. You know, I 25 imagine she meant permanent because I'm using a cane.</p>

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46 to 49

<p style="text-align: right;">Page 46</p> <p>1 Q. So did -- have you -- since that time have you 2 ever gone back to any CSL plasma center? 3 A. No, ma'am. 4 Q. So did anyone at CSL Plasma ever talk to you 5 about being deferred because of behavior? 6 A. No, ma'am. 7 Q. So it was the first time you learned that your 8 file says you're permanently deferred because of behavior 9 when you saw the notes here? 10 A. Pretty much. I mean, I did learn of that 11 earlier. But, I mean, you know, it's just ridiculous. 12 It's ridiculous, behavior. 13 Q. Because your behavior was not bad? Is that 14 what you're saying? 15 A. Because that -- what behavior? What did I do 16 wrong? 17 Q. You told me you shook your finger and said, 18 you'll be sorry? 19 A. Yeah. But that wasn't a threat as far as 20 violence or physical or anything like that. No, I 21 mean -- 22 Q. Do you think she could understood -- have 23 understood it to be a threat of that? 24 A. You know, I mean, when somebody is wrong and 25 you want to correct them, sometimes you do use hand</p>	<p style="text-align: right;">Page 47</p> <p>1 gestures, you know, like with a child. 2 Q. What about saying, you will be sorry? Do you 3 think she could have understood that to mean that you 4 were threatening her physically? 5 A. She shouldn't have. 6 Q. Why not? 7 A. I mean, I didn't mean it like that, for sure. 8 You know, I'm not a violent person, to start off with. 9 Q. But do you think threatening someone is a 10 reason to get deferred? 11 A. You know, I needed to talk to the supervisor. 12 I needed to talk to somebody above her, because I wasn't 13 going to get anywhere with her, obviously. 14 Q. Did you ask her if you could talk to a 15 supervisor? 16 A. No. No, I called instead. I didn't want to 17 talk to her. I called. That's why -- decided I would 18 go -- I'm going to call somebody to talk to somebody. 19 Q. Did anyone laugh at you when you were at the 20 center? 21 A. I hope not. 22 Q. But not that you remember? 23 A. That I remember. 24 Q. Did anyone say anything that belittled you when 25 you were at the center?</p>
<p style="text-align: right;">Page 48</p> <p>1 A. Not to my recollection. 2 Q. Do you believe that businesses have the right 3 to ban someone from their location if they're 4 threatening? 5 A. Yeah. In what way, though? Violent way? Is 6 that what you're asking me? 7 Q. Just any sort of threat in general. 8 A. You know, there's a process. You know, people 9 have rights, you know. And when you're not given that 10 right -- you know, I had a right to speak to a 11 supervisor. I should have been given that right. 12 Q. But when you were there, you didn't ask to 13 speak to a supervisor -- 14 A. No, but I called. Minutes later I called. I 15 wasn't going to tell her that. 16 Q. Why not? 17 A. Come on. 18 Q. You think she wouldn't have let you? 19 A. You know what, lady? That -- you know, her 20 ignorance was that thick. I was not going to talk to 21 her. 22 Q. Why do you say she was ignorant? 23 A. The fact that she was discriminating against me 24 without even -- you know, made up her mind already, I 25 couldn't do something without even allowing me or asking</p>	<p style="text-align: right;">Page 49</p> <p>1 me to do it, you know. 2 That's somebody that -- you know, in the 3 profession that they're in -- you know, being a nurse, 4 too, myself, you know, I understand you don't -- you 5 know, you can't make assumptions like that, you know. 6 How does she know I couldn't transfer? 7 She didn't give me an opportunity to. I'd done it 8 before. And according to these notes, said I can do it, 9 too. 10 Q. Did you tell her you transferred before? 11 A. Probably not. Probably not. Like I said, she 12 sounded like she had made up her mind already, you know. 13 I don't know why she picked on -- didn't like me that 14 day. I don't know. Because of my cane, I guess. 15 Q. So she said you -- she said she was deferring 16 you, and then you basically just walked out; is that 17 right? 18 A. Well, I mean, what else -- what other option 19 did I have at the time? She told me, you're deferred for 20 these reasons. And it's like, okay, you know. I'm being 21 humble and accepting what you're telling me because 22 you're in charge. But I know there's another -- somebody 23 above you. So I decided to go call as soon as I left. 24 Q. How long did you have to sit in the car and 25 wait for your wife?</p>



Reynaldo Vargas  
June 26, 2017

10 to 13

<p style="text-align: right;">Page 10</p> <p>1 A. We've talked about the conditions guideline. 2 That's one of those things. Health assessment, that's 3 another. 4 Q. And what is the health assessment? 5 A. The health assessment is a hands-on head-to-toe 6 assessment that is provided to new donors and for annual 7 donors. 8 Q. And how does the health assessment differ from 9 the conditions guidelines? Help me understand the 10 difference between the two. 11 A. Sure. Absolutely. The health assessment is 12 actually a hands-on portion, head-to-toe assessment, 13 where we're looking at our donor and evaluating what's in 14 front of us. The conditions guideline is a guideline 15 that we use to reference certain medical conditions when 16 they come about. 17 Q. And is the health assessment guideline written 18 anywhere? 19 A. The health assessment is written, correct. 20 Yes, it is. 21 Q. And are the protocols for taking the health 22 assessment written anywhere? 23 A. Yes. 24 Q. And do you provide a written copy of those 25 protocols to the individuals that you are training?</p>	<p style="text-align: right;">Page 12</p> <p>1 A. Yes. They're not left alone till they're 2 completely signed off and ready to be on their own. And 3 that's with physician approval. 4 Q. And if you had to estimate an average amount of 5 time it takes someone to be trained, what would that 6 average be as an estimate? 7 A. Three weeks at an estimate. That's -- and 8 that's -- like I said, it's based on the individual. 9 Q. And are staff supposed to refer to the written 10 health assessment protocols as necessary? 11 A. They are available as necessary. 12 Q. And are staff supposed to refer to the 13 conditions guidelines as necessary? 14 A. They are available as necessary. 15 Q. Mr. Vargas, have you ever participated in any 16 Americans with Disabilities Act or ADA training? 17 A. No formal training. 18 Q. Have you ever had any training about avoiding 19 disability discrimination? 20 A. Not -- no formal training regarding that. 21 Q. And did you know that you are not supposed to 22 discriminate against people with disabilities? 23 MS. WILLING: Objection. Calls for a 24 legal conclusion. 25 You can still answer.</p>
<p style="text-align: right;">Page 11</p> <p>1 A. It is something that they read, and it is 2 available to them at any time. 3 Q. And do you train the medical staff associates? 4 A. Yes, I do. 5 Q. Did you train Michelle Mailey? 6 A. I had some part in her training, not a hundred 7 percent. 8 Q. What type of written documentation do you 9 provide individuals that you are training? 10 A. The written documentation that's provided to 11 our trainees is -- is a document that addresses every 12 specific area of whatever part of the training is -- is 13 occurring. 14 Q. How many days does it take to train someone to 15 be an MSA? 16 A. It's based on the individual receiving the 17 training. 18 Q. Are there any tests or exams that you provide 19 to the MSA in training? 20 A. There is two assessments that are provided. 21 And they also have knowledge questions that have to be 22 addressed with the trainee, and they have to be 23 proficient on it. 24 Q. And do they shadow people as part of their 25 training?</p>	<p style="text-align: right;">Page 13</p> <p>1 A. I'm aware of that. 2 Q. (By Ms. Davis) And how did you know that you 3 weren't supposed to discriminate against people with 4 disabilities? 5 A. It's -- it's posted everywhere you go. 6 Q. Is it posted inside the center? 7 A. I don't recall at this moment. 8 Q. And so you say that it's posted everywhere you 9 go. Where do you go that you may see it? 10 A. It -- I'm not going to get into specifics as to 11 where. But, I mean, it seems like everywhere you walk to 12 nowadays, there's a sign regarding disabilities. 13 Q. Do you mean outside the center when you're in 14 public? 15 A. Absolutely. 16 Q. Recall any place in the center that something 17 like that is posted? 18 A. I do not recall at this moment. 19 Q. And did you ever receive any training on how to 20 interact with prospective donors with disabilities? 21 A. In regards to our medical training, that's 22 something that's -- that's in there. 23 Q. And where is that? 24 A. I'm -- I'm not exactly sure where it's at. 25 It's something that it -- it's mentioned in the</p>

Reynaldo Vargas  
June 26, 2017

26 to 29

<p style="text-align: right;">Page 26</p> <p>1 A. Yes, they have.</p> <p>2 Q. And were they allowed to speak with your</p> <p>3 supervisor with corporate?</p> <p>4 A. Absolutely.</p> <p>5 Q. What happens when someone says that they want</p> <p>6 to speak to someone above you?</p> <p>7 A. Then at that point I ask them to wait where</p> <p>8 we're at, and I go get my superiors and have them come</p> <p>9 speak to the donor.</p> <p>10 Q. Is that common protocol, to allow dissatisfied</p> <p>11 donors to talk to supervisors?</p> <p>12 A. If they request it, yes.</p> <p>13 Q. -- donors ever get angry?</p> <p>14 A. Yes, ma'am.</p> <p>15 Q. And how would you know that they were angry?</p> <p>16 A. When they raise their voice, start using</p> <p>17 profane language on occasion, that would indicate that</p> <p>18 they're angry.</p> <p>19 Q. What would you do if that happened?</p> <p>20 A. I maintain as calm as possible and allow the</p> <p>21 donor to have their say. And if they want to speak to a</p> <p>22 superior, by all means, give them that opportunity.</p> <p>23 Q. Did you have to report that behavior to a</p> <p>24 supervisor?</p> <p>25 A. I would document it in their donor data file.</p>	<p style="text-align: right;">Page 28</p> <p>1 Q. Explain that to me. If it's a medical</p> <p>2 condition, you are the last person that they can complain</p> <p>3 to? Is that --</p> <p>4 A. They can complain to -- I'm sorry. I'll let</p> <p>5 you finish.</p> <p>6 Q. Is that what I'm understanding?</p> <p>7 A. What I'm saying is, at the center level, if</p> <p>8 it's a medical condition and I defer a donor because of a</p> <p>9 medical condition, then they would have to take it to</p> <p>10 maybe corporate at that point to be able to see if that</p> <p>11 determination could be made. How corporate would handle</p> <p>12 that, I cannot answer.</p> <p>13 Q. Are you or MSAs authorized to defer someone</p> <p>14 from donating for a reason that's not listed on the</p> <p>15 medical staff reference - conditions guidelines?</p> <p>16 A. I would have to see what the reason was.</p> <p>17 Q. Can you think of any examples that would -- you</p> <p>18 would be authorized to defer someone for a condition</p> <p>19 that's not listed on the medical staff reference -</p> <p>20 conditions guidelines?</p> <p>21 A. I can't think of anything off the top of my</p> <p>22 head.</p> <p>23 Q. Ever been threatened while at work?</p> <p>24 A. Yes, ma'am.</p> <p>25 Q. When was that?</p>
<p style="text-align: right;">Page 27</p> <p>1 Q. If a donor just calls CSL Plasma directly on</p> <p>2 the phone and asks to speak to a supervisor, who would</p> <p>3 that call typically be directed to?</p> <p>4 A. Based on who they're speaking with and if they</p> <p>5 want to speak to somebody superior than myself, then one</p> <p>6 of the assistant center managers or the center manager.</p> <p>7 Q. When donors were referred, would you tell them</p> <p>8 or would an MSA tell them the reason why they were being</p> <p>9 deferred?</p> <p>10 A. Absolutely.</p> <p>11 Q. -- donors ever try to prove that the reason for</p> <p>12 the deferral was wrong?</p> <p>13 A. I'm not sure how to answer that question. I</p> <p>14 mean, do people argue? Yes.</p> <p>15 Q. And what happens when a person argues?</p> <p>16 A. If the deferral is set in place for a reason,</p> <p>17 it does not change the end result. If a donor is</p> <p>18 deferred, a donor is deferred because of the condition or</p> <p>19 the reason why the donor is deferred.</p> <p>20 Q. What if the reason for the deferral was wrong?</p> <p>21 A. Then at that point it's not my determination to</p> <p>22 make.</p> <p>23 Q. Whose determination to make is it?</p> <p>24 A. If it's a medical condition, then it doesn't go</p> <p>25 above medical staff.</p>	<p style="text-align: right;">Page 29</p> <p>1 A. I can't recall specifically. Approximately six</p> <p>2 months ago.</p> <p>3 Q. It was at CSL Plasma?</p> <p>4 A. Yes, ma'am.</p> <p>5 Q. What happened?</p> <p>6 A. Donor was upset because he couldn't donate.</p> <p>7 Balled up his fists and attempted to -- attempted to have</p> <p>8 a piece of paper in his hand and make like he was going</p> <p>9 to strike me, but then he changed his mind.</p> <p>10 Q. What happened after that?</p> <p>11 A. I allowed him to walk out and go about his way.</p> <p>12 Q. Was that a physical threat?</p> <p>13 A. It never made it to that point.</p> <p>14 Q. When you say he had his fist balled up, did it</p> <p>15 look like he was going to try to strike you?</p> <p>16 A. It appeared that way.</p> <p>17 Q. Did you call the police?</p> <p>18 A. We did.</p> <p>19 Q. And was there a police report made?</p> <p>20 A. I -- not sure if the police were able to</p> <p>21 contact that donor once he left the facility.</p> <p>22 Q. Did you make note of it in his files?</p> <p>23 A. Yes, ma'am.</p> <p>24 Q. And did you tell a supervisor?</p> <p>25 A. Yes, ma'am.</p>



Reynaldo Vargas  
June 26, 2017

42 to 45

<p style="text-align: right;">Page 42</p> <p>1 Q. Can you think of another example of a time you 2 deferred someone for something not listed in the 3 conditions guidelines? 4 A. Not specifically. 5 Q. Can you think of something generally? 6 A. Out-of-range values, like total protein. 7 Q. How did you know to defer somebody for 8 out-of-range values? 9 A. Because our SOP gives us a minimum and a 10 maximum value. And if they fall outside that range, then 11 they are deferred for the day. 12 Q. Which SOP is that? 13 A. Number-wise, I cannot give you, but it talks 14 about total protein and hematocrit. 15 Q. Is it a SOP about vital signs? 16 A. I think it's specifically reading protein and 17 hematocrit. 18 Q. Is there an SOP about the temperature? 19 A. Yes, there is. 20 Q. Donor you described earlier, balled up his 21 fist, did he get permanently deferred? 22 A. Yes, he did. 23 Q. Who permanently deferred him? 24 A. Who permanently deferred him? 25 Q. Yes.</p>	<p style="text-align: right;">Page 44</p> <p>1 individuals that need them for some other condition? 2 A. It's based on the condition and what aggravates 3 that condition. 4 Q. And does having a service animal aggravate a 5 condition that would prevent them from donating? 6 A. Again, each specific condition would have to be 7 looked at individually for me to be able to answer that 8 question. 9 Q. -- a person has an anxiety disorder and uses a 10 service animal, are they allowed to donate? 11 A. That's based on interviewing the donor. 12 Q. What -- what would you look for in that 13 interview? 14 A. Donor response, what aggravates -- what sets 15 off the anxiety. 16 Q. Ask the donor questions about what sets off 17 their anxiety? 18 A. Absolutely. 19 Q. What type of answers would you be looking for 20 that would allow them to donate? 21 A. It's -- it's not just the answer. I would have 22 to see donor response as well. 23 Q. If the donor was called, would that be a good 24 indicator that the donor would be able to donate if they 25 met all other conditions?</p>
<p style="text-align: right;">Page 43</p> <p>1 A. I did. 2 Q. -- tell him that he was permanently deferred? 3 A. One more time with that question, please. 4 Q. Did you tell him that he was permanently 5 deferred? 6 A. At that point when he walked out, I did not. 7 When he returned, somebody else advised him he was 8 permanently deferred. 9 Q. Did he return to donate? 10 A. He attempted. 11 Q. Had you ever had a donor that uses a service 12 animal? 13 A. Have I ever? No, not specifically. 14 Q. Do you know CSL Plasma's guidelines on service 15 animals? 16 A. I wouldn't be able to give it to you word for 17 word. 18 Q. What -- what does the guideline say, generally? 19 A. It just says service animals for -- I believe 20 seeing eye dogs are acceptable. Everything else has to 21 be based on condition. 22 Q. And why service animals are based on 23 condition -- let me rephrase that. Do you know why 24 service animals are accepted for individuals who need 25 them as a seeing eye dog and are not accepted for</p>	<p style="text-align: right;">Page 45</p> <p>1 A. Again, my interpretation of calm would be 2 different than anybody else's, yours or mine. 3 Q. If your interpretations of calm were met, would 4 that donor be able to donate if they met all other 5 conditions? 6 A. Again, I would have to have that donor in front 7 of me to make that determination. 8 Q. -- agree that companies should not discriminate 9 against people with disabilities? 10 A. One more time with the question. 11 Q. Do you agree that companies should not 12 discriminate against people with disabilities? 13 A. I agree. 14 Q. Why do you believe that? 15 A. Because I believe everybody needs to get a fair 16 shot at the opportunity that's in front of them. 17 Q. Is there an SOP about service animals? 18 A. There's not a specific SOP about service 19 animals. 20 Q. What are you looking for when you interview 21 somebody regarding anxiety? 22 A. The first thing I would have to have is a donor 23 in front of me to even attempt to look at what I'm 24 looking for. 25 Q. Are there questions you're supposed to ask?</p>

Amy Wolfe  
July 07, 2017

1

Page 1

THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
CORPUS CHRISTI DIVISION

MARK SILGUERO,	)	
Plaintiff,	)	
	)	
and	)	
	)	
AMY WOLFE,	)	
Intervening Plaintiff,	)	
	)	
v.	)	CIVIL ACTION NO.
	)	2:16-CV-00361
	)	
CSL PLASMA INC.,	)	
DEFENDANT.	)	

\*\*\*\*\*

ORAL DEPOSITION OF

AMY WOLFE

JULY 7, 2017

\*\*\*\*\*

ORAL DEPOSITION of AMY WOLFE, produced as a witness at the instance of the DEFENDANT, and duly sworn, was taken in the above-styled and numbered cause on JULY 7, 2017, from 10:06 a.m. to 11:54 a.m., before Stephanie M. Harper, RPR, CSR in and for the State of Texas, recorded by machine shorthand, at the offices of DISABILITY RIGHTS TEXAS, 1500 McGowen, SUITE 100, Houston, Texas, pursuant to the Federal Rules of Civil Procedure and the provisions stated on the record or attached hereto; that the deposition shall be read and signed before any notary public.

JOB NO. 244923

U.S. LEGAL SUPPORT  
713-653-7100

Amy Wolfe  
July 07, 2017

10 to 13

<p style="text-align: right;">Page 10</p> <p>1 Q. And what year did you graduate high school?</p> <p>2 A. 2014.</p> <p>3 Q. And immediately after that, you came to</p> <p>4 Houston for college?</p> <p>5 A. Yes, ma'am.</p> <p>6 Q. Now, are you still taking classes at the</p> <p>7 University of Houston?</p> <p>8 A. Yes, ma'am.</p> <p>9 Q. What are you studying?</p> <p>10 A. Psychology, with a minor in biology.</p> <p>11 Q. Do you have an expected date of graduation?</p> <p>12 A. August of this year.</p> <p>13 Q. Close. Exciting.</p> <p>14 A. Yeah.</p> <p>15 Q. So are you finishing up summer classes, then?</p> <p>16 A. Yes, ma'am. Two more to go, and I will be</p> <p>17 done.</p> <p>18 Q. Congratulations.</p> <p>19 Do you know what you're doing after you</p> <p>20 graduate?</p> <p>21 A. I'm hoping to get into the forensics field.</p> <p>22 Houston has the Institute of Forensics, and I'd really</p> <p>23 like an internship there if I can manage to snag one.</p> <p>24 Q. So that would be like lab work?</p> <p>25 A. Lab work, autopsy assistant, crime scene.</p>	<p style="text-align: right;">Page 12</p> <p>1 A. For about a month now.</p> <p>2 Q. And where did you work before that?</p> <p>3 A. Before that, I had a brief stint at the Mad</p> <p>4 Potter.</p> <p>5 Q. And what is that?</p> <p>6 A. It's a paint your own pottery place.</p> <p>7 Q. And where did you work before that?</p> <p>8 A. Before that, I worked for the University of</p> <p>9 Houston.</p> <p>10 Q. What were you doing for them?</p> <p>11 A. I was a student worker at printing and postal.</p> <p>12 Q. Since you graduated high school, have you</p> <p>13 pretty much always been taking college classes and then</p> <p>14 just doing the jobs on the side?</p> <p>15 A. Yes, ma'am.</p> <p>16 Q. Do you receive any sort of student loans,</p> <p>17 government aid to pay for your college?</p> <p>18 A. Yes, ma'am. I receive loans and grants</p> <p>19 through FASFA and also the Texas Workforce Commission.</p> <p>20 Q. What is the Texas Workforce Commission?</p> <p>21 A. They were previously known as DARS, or the</p> <p>22 disability advocates. I cannot remember for the life</p> <p>23 of me the anagram [verbatim].</p> <p>24 Q. So it's some sort of program that gives money</p> <p>25 to students with disabilities?</p>
<p style="text-align: right;">Page 11</p> <p>1 Q. That sounds exciting.</p> <p>2 A. Yeah.</p> <p>3 Q. Other than your classes at the University of</p> <p>4 Houston, have you ever received any other vocational</p> <p>5 training or post high school training?</p> <p>6 A. No, ma'am.</p> <p>7 Q. Have you ever served in the military?</p> <p>8 A. No, ma'am.</p> <p>9 Q. Are you currently employed?</p> <p>10 A. Yes, ma'am.</p> <p>11 Q. And where do you work?</p> <p>12 A. I work at Urban Tails.</p> <p>13 Q. And what is Urban Tails?</p> <p>14 A. We're a dog boarding and daycare facility, and</p> <p>15 we also do training.</p> <p>16 Q. And what do you do there?</p> <p>17 A. I'm the head trainer, and I am a daycare</p> <p>18 assistant and a pet attendant.</p> <p>19 Q. Is that a fun job?</p> <p>20 A. It -- yes, it is.</p> <p>21 Q. We take our dog to daycare every day, so it</p> <p>22 seems like you guys have fun. I'm always a little</p> <p>23 jealous.</p> <p>24 A. It really is.</p> <p>25 Q. And how long have you worked there?</p>	<p style="text-align: right;">Page 13</p> <p>1 A. Yes, ma'am, and places them in jobs and...</p> <p>2 Q. So did they place you in jobs?</p> <p>3 A. Not yet. But they do help with tuition.</p> <p>4 Q. And how did you hear about that program?</p> <p>5 A. A friend of mine suffers from a disability.</p> <p>6 He was born completely deaf, and they helped him.</p> <p>7 Q. And you have a service dog; that's correct?</p> <p>8 A. Yes, ma'am.</p> <p>9 Q. And what's his name?</p> <p>10 A. Harley.</p> <p>11 Q. Is this your first service dog?</p> <p>12 A. Yes, ma'am.</p> <p>13 Q. And when did you get Harley?</p> <p>14 A. In May of 2015.</p> <p>15 Q. And what made you decide to get a service dog?</p> <p>16 A. My mother's a psychiatric nurse. And we</p> <p>17 discussed it because I had tried many other means of</p> <p>18 treatments, and they were all falling short.</p> <p>19 Q. So what's the process for going about getting</p> <p>20 a service dog?</p> <p>21 Did you have to apply or ask someone, or how</p> <p>22 does that work?</p> <p>23 A. It depends whether you go through a program or</p> <p>24 owner training. There aren't many programs available</p> <p>25 for people suffering civilian PTSD. And since I'm also</p>

Amy Wolfe  
July 07, 2017

14 to 17

<p style="text-align: right;">Page 14</p> <p>1 on the spectrum, it was considered better for me to 2 train my own or go through training with him so he 3 would be more personalized. So he is owner trained. 4 The basics for a service dog is that they 5 know at least one task that mitigates the disability 6 and the handler is disabled. And they are trained in 7 public access, which is a general good behavior 8 guideline. 9 Q. So where did you get Harley? 10 A. He was adopted. I specifically decided I 11 needed a -- a service dog. And normally some people go 12 through breeders, but I wanted to try the adoption 13 route. 14 Q. So you went and found him at like an adoption 15 center where there were other dogs and... 16 A. Yes, ma'am. 17 Q. So the decision to get a service dog was you 18 talking to your mom, and then you decided to go out and 19 pick him up at the center? 20 A. I also discussed it with my doctor, who 21 supported it. 22 Q. And what doctor was that, or what was the 23 doctor's name? 24 A. Russell Phillips. 25 Q. And did you have any help in training Harley?</p>	<p style="text-align: right;">Page 16</p> <p>1 attacks? 2 A. Yes, ma'am. 3 Q. And what were the others? 4 A. Migraines, panic attacks, disassociations, or 5 I suffer from chronic pain. So I will have random 6 chronic pain fits almost. I'm just -- where I'll be in 7 a lot of pain. And Harley's -- Harley will alert me a 8 minute or so before those hit so I can sit down. 9 Q. So he knows you're going to be in pain a 10 couple minutes before you do? 11 A. Yes, ma'am. 12 Q. And what does he do when he senses that? 13 A. He stands up, and he'll lean into my legs, if 14 it's not going to be too severe. It gives me a moment 15 to brace. Or if it's going to be more severe, if -- I 16 believe how we shaped it was if there was more a chance 17 of it being severe, he'll hop in my lap, and he'll 18 start performing deep pressure therapy. 19 Q. And how does he perform deep pressure therapy? 20 A. He puts his weight into my lap, and he'll 21 either focus it in his paws or he'll lean against my 22 chest. 23 Q. And other than just kind of giving you a 24 heads-up that this is coming, does he do anything to 25 help mitigate?</p>
<p style="text-align: right;">Page 15</p> <p>1 A. Not directly. 2 Q. What do you mean by that? 3 A. I'm in several disabled communities with a lot 4 of individuals who have service dogs and who have 5 trained service dogs, and I did a lot of research on 6 different methodologies, and basically I came from -- I 7 worked at a training program based on what he responded 8 to and was happy doing. 9 Q. Had you owned dogs before growing up? 10 A. Yes, ma'am, all the time. 11 Q. Had you trained a dog before Harley? 12 A. I had worked with my mother on basic obedience 13 and manners for ex-racing greyhounds. We fostered for 14 multiple years in Lubbock. Them behaving better upped 15 their chances of adoption, so... 16 Q. So you trained the racing greyhounds and then 17 had -- helped them get placed in other homes? 18 A. Yes, ma'am. 19 Q. So what is Harley trained to do for you? 20 A. His biggest tasks I call "medical alert" as an 21 umbrella. He alerts me to cortisol spikes, which 22 accompany my migraines, many pain attacks and panic 23 attacks and disassociation. 24 Q. So a spike in cortisol could indicate a number 25 of things, which you said include migraines and anxiety</p>	<p style="text-align: right;">Page 17</p> <p>1 A. The deep pressure therapy. And he also is 2 trained to -- in case of a panic attack, if I start 3 scratching at myself or pulling my hair, he will 4 redirect my hand to his head, so I pet him instead. 5 Q. Does he also sense the panic attacks about a 6 minute or so before? 7 A. Yes, ma'am. Those are also indicated with the 8 cortisol spikes. And he will actually let me know if I 9 need to leave a room. Say I'm in a large class, and 10 I'm going to have a really severe panic attack. I'm 11 not currently on medication, but when I was, he was 12 trained to settle down after I had taken my medication 13 if I was at a certain level. But if the medication 14 didn't work, he would not settle down until I left the 15 classroom physically. And that was how he let me know 16 you need to leave this situation to be safe. 17 Q. And you said that was when you were on 18 medication? 19 A. Yes, ma'am. 20 Q. Does he still do that -- sorry, does he still 21 indicate if you need to leave a room now? 22 A. Yes, ma'am. 23 Q. How often do you get panic attacks? 24 A. It can be very situational. Before I got 25 Harley, it was multiple times a day. With Harley, it's</p>

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18 to 21

<p style="text-align: right;">Page 18</p> <p>1 once, twice a week, maybe. If it's a harder month, I 2 might have two or three a week. If it's an easier 3 month, I might have none for a couple of weeks. 4 Q. And you said they're situational? 5 A. Yeah. 6 Q. What kinds of things tend to trigger a panic 7 attack? 8 A. Being in large crowds. 9 Q. Anything else? 10 A. Public speaking and that sort of thing. Like 11 I'm walking out and it -- dark after night -- or 12 walking outside after dark, it can happen. And then 13 sometimes they're random, but those are rarer. 14 Q. So anything other than large crowds, public 15 speaking, or being outside after dark that kind of tend 16 to trigger panic attacks? 17 A. If I get overwhelmed sensationally. So at 18 music concerts or something like that. 19 Q. Anything else? 20 A. Not that I can think of. 21 Q. And when you say "large crowds," does that 22 tend to be -- like, I'm thinking like a ballpark type 23 large crowds, or is that more of like even a large 24 classroom type large crowd? 25 A. Large classrooms would be -- yeah, in the</p>	<p style="text-align: right;">Page 20</p> <p>1 disability is anxiety disorder? 2 A. Yes, ma'am. 3 Q. And when were you first diagnosed with anxiety 4 disorder? 5 A. It's been a while. I believe it was the first 6 couple of years of high school. But it became really 7 disabling the first year of college. 8 Q. And were you diagnosed by a doctor? 9 A. Yes, ma'am. 10 Q. And what doctor was that? 11 A. Dr. Phillips. 12 Q. And was this a doctor back at your home or at 13 college or -- 14 A. At home. 15 Q. And what -- what are your symptoms? 16 Is it just the attacks, or is it anything 17 else? 18 A. Panic attacks. Sometimes I'll feel a 19 tightness in my chest, but it's mostly just the panic 20 and the anxious thoughts. 21 Q. And what -- you -- you said you started 22 college in 2014? 23 A. Yes, ma'am. 24 Q. And you got Harley -- would -- would that have 25 been the end of your first year of college or --</p>
<p style="text-align: right;">Page 19</p> <p>1 hundreds or in large retail stores like Sam's Club at 2 rush hour. 3 Q. And do you always have Harley with you? 4 A. Yes, ma'am. There are times I will leave him 5 at home if his health is -- like, if he's had like a 6 sick day or something. But that's very rare. And most 7 of those days I don't leave the house without him. If 8 he's in the same building with me, say I'm going to the 9 doctor for a CT or something, he can be in a different 10 room, and I'm all right. 11 Q. I imagine if he's in a different room, he 12 wouldn't be able to tell if your cortisol is spiking; 13 is that right? 14 A. Yeah. He was with my boyfriend the other day, 15 and he did alert when I was out of the room. But I'm 16 not sure if that was towards me. But as soon as I got 17 back, he performed deep pressure therapy. 18 Q. So having him close by, say, in the next room 19 is helpful to you to help not have panic attacks, but 20 he can't alert to the cortisol? 21 A. Yes, ma'am. 22 Q. And you understand you're bringing a 23 disability discrimination claim; is that correct? 24 A. Yes, ma'am. 25 Q. And for the purposes of this claim, the</p>	<p style="text-align: right;">Page 21</p> <p>1 A. Yes, I believe so. May of 2015. 2 Q. And when you were first diagnosed with anxiety 3 disorder, were you on any medications? 4 A. I was on -- yes. I'm -- I'm trying to 5 remember the name. I can't for the life of me remember 6 the name. Sorry. 7 Q. It's okay. They're all very complicated and 8 hard to pronounce. 9 A. Yeah. 10 Q. And then you said at some point, you stopped 11 taking medication, and you got Harley. Did you stop 12 taking medication before you got Harley? 13 A. After. 14 Q. After. 15 So would you say having Harley meant that you 16 didn't need the medication? 17 A. It meant I needed it less. And then I was 18 able to come fully off of it. 19 Q. Did you start taking medication in high school 20 when you were first diagnosed? 21 A. Yes, ma'am. 22 Q. Do you take -- I know you don't remember which 23 one. Did you take the same one all the way through, or 24 did you kind of bounce around to different ones? 25 A. I took one pretty steadily through high</p>



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22 to 25

<p style="text-align: right;">Page 22</p> <p>1 school, but when I went to college and things, i.e., 2 got worse. I did move to Klonopin, which is a higher 3 strength. 4 Q. And are you currently taking any medications? 5 A. Yes. 6 Q. And what are you currently taking? 7 A. Prozac. 8 Q. Is that the only thing you're taking? 9 A. Yes, ma'am. 10 Q. And when did you start that up? 11 A. I want to say September of 2016. 12 Q. And you've also been diagnosed with PTSD; is 13 that correct? 14 A. Yes, ma'am. 15 Q. And when were you diagnosed with that? 16 A. 20-- I believe really early 2015, like 17 January. Maybe a little earlier. 18 Q. And did you take any medications for your PTSD 19 specifically? 20 A. Just the ones for my anxiety. 21 Q. And do you see a -- a psychologist and/or a 22 psychiatrist? 23 A. I see the school psychiatrist. 24 Q. How long have you been seeing the school 25 psychiatrist?</p>	<p style="text-align: right;">Page 24</p> <p>1 Q. And I believe in this lawsuit, you've said 2 that your anxiety substantially limits major life 3 activities; does that sound right? 4 A. Yes, ma'am. 5 Q. What activities does it limit? 6 A. It limits most of them: leaving the house, 7 eating, interacting with people. It was interacting 8 with work in a negative way, and school. 9 Q. Are you going to graduate early from college? 10 A. Yes, ma'am. 11 Q. Took you, what, three years to get through? 12 A. Yeah. 13 Q. Impressive. 14 A. Thank you. 15 Q. Did you take summer school all the way 16 through, then? 17 A. Yeah, and I graduated with a semester already 18 done almost or a little over a semester done during 19 high school. 20 Q. Nice. Did you ever have to take any time off 21 school because of your anxiety or PTSD? 22 A. No, ma'am. I probably should have, but... 23 Q. When was the last time you had an anxiety 24 attack? 25 A. A couple of days ago.</p>
<p style="text-align: right;">Page 23</p> <p>1 A. Since September. 2 Q. Of 2016? 3 A. Yes. Sorry. 4 Q. That's okay. Were you seeing another 5 psychiatrist before that? 6 A. I've seen a few, but I think the last one 7 before that was also at the university, their 8 counseling center. But I cannot remember his name. 9 Q. And what's the name of the one you're seeing 10 currently? 11 A. Dr. Stern. 12 Q. Have you seen a psychiatrist maybe on and off 13 since you were first diagnosed with anxiety? 14 A. Dr. Phillips was the main treatment. 15 Q. And he is a psychiatrist? 16 A. He's a general care practitioner, or he was my 17 primary care. 18 Q. Do you have a current -- I don't want to 19 use -- misuse medical terms. Is there a sense that 20 your anxiety will get better in the future, or is that 21 not something that you talk about? 22 A. There's the possibility. I have improved with 23 Harley. But if I were to take away Harley, I don't 24 know if I would get worse again or stay where I'm at. 25 But I have seen an improvement with the service dog.</p>	<p style="text-align: right;">Page 25</p> <p>1 Q. And what triggered that one? 2 A. One of the dogs at work, one of our puppies, 3 nipped at my neck, which is one of my triggers. Just 4 out of nowhere. He was trying to play. I don't blame 5 the little one, but Harley was there and brought me 6 down from it quickly. 7 Q. So he comes to work with you? 8 A. Yes. 9 Q. And how are you generally in hospitals; is 10 there anything in a hospital or medical facility that 11 would trigger a panic attack? 12 A. No, ma'am. I actually spent seven hours in 13 one a few days ago with no anxiety. 14 Q. And have you talked to Dr. Stern about your 15 service animal, I assume? 16 A. Yes, ma'am. 17 Q. And he -- does he approve of it; does he 18 disapprove, any -- 19 A. He approves. He sees the benefit. 20 Q. And has he prescribed anything other than the 21 Prozac? 22 A. We did try a couple of antianxiety 23 medications -- one for antianxiety and one that's meant 24 to stop nightmares -- but they did not work for me. 25 Q. And around what time were you trying those</p>

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26 to 29

<p style="text-align: right;">Page 26</p> <p>1 medications?</p> <p>2 A. Actually that was during summer. So I saw</p> <p>3 Dr. Stern earlier than September. I apologize.</p> <p>4 Q. That's fine.</p> <p>5 A. That's right. He had me on them last summer</p> <p>6 of 2016.</p> <p>7 I believe I went to another doctor around</p> <p>8 September, and that's why I was thinking...</p> <p>9 Q. Do you think by October of 2016, you were not</p> <p>10 on any medications; does that sound right?</p> <p>11 A. Yes, ma'am.</p> <p>12 Q. Because by that time you were off of the ones</p> <p>13 you had started in the summer?</p> <p>14 A. Yes. And then I started Prozac a few weeks</p> <p>15 after.</p> <p>16 Q. Why the gap?</p> <p>17 Why not start Prozac right away?</p> <p>18 A. It took some time to get in to see my</p> <p>19 psychiatrist. Beginning of school, everyone rushes in.</p> <p>20 Q. So you went to CSL in the Houston location in</p> <p>21 about October 2016; does that sound right?</p> <p>22 A. Yes, ma'am.</p> <p>23 Q. Had you ever donated plasma before?</p> <p>24 A. No, ma'am.</p> <p>25 Q. How did you hear about CSL?</p>	<p style="text-align: right;">Page 28</p> <p>1 A. Not really. I looked -- I Googled a couple of</p> <p>2 things and read other people's experience.</p> <p>3 Q. So what made you decide to go in that day?</p> <p>4 A. I think it was just convenient.</p> <p>5 Q. Was it a weekend, a school day, if you</p> <p>6 remember?</p> <p>7 A. I can't remember. I think it was a school day</p> <p>8 for some people, but I didn't have class that day.</p> <p>9 Q. And why did you go to CSL, as opposed to</p> <p>10 another donation center?</p> <p>11 A. They were close and had some good reviews.</p> <p>12 Q. Did you know that people get paid to donate</p> <p>13 plasma before you went?</p> <p>14 A. Yes, ma'am.</p> <p>15 Q. And were you aware that CSL defers a lot of</p> <p>16 people that want to donate?</p> <p>17 A. No, I was not.</p> <p>18 Q. Have you donated plasma anywhere since you</p> <p>19 went to CSL that day?</p> <p>20 A. No, ma'am.</p> <p>21 Q. Why not?</p> <p>22 A. I've been anxious about complication and</p> <p>23 worried that I would be turned down. I didn't want to</p> <p>24 go through using all that energy just to be turned down</p> <p>25 again, and -- though I would still like to donate.</p>
<p style="text-align: right;">Page 27</p> <p>1 A. Through Google.</p> <p>2 Q. And how did you know that you could do -- how</p> <p>3 did you know that you could donate plasma?</p> <p>4 A. I have some friends who are in my disability</p> <p>5 groups who use plasma and were discussing donations or</p> <p>6 whose conditions require that they use plasma.</p> <p>7 Q. And what kind of conditions require the use of</p> <p>8 plasma?</p> <p>9 A. I cannot remember off the top of my head right</p> <p>10 now.</p> <p>11 Q. And so you knew that people used plasma. How</p> <p>12 did you know that you could donate plasma?</p> <p>13 A. I believe I heard of it donating blood.</p> <p>14 Q. And what did you know about the process before</p> <p>15 you decided to go that day?</p> <p>16 A. Not much, other than they take the plasma out</p> <p>17 and put the blood back in, basically. That it took</p> <p>18 about 30 minutes to an hour.</p> <p>19 Q. Did you know anyone who had donated plasma?</p> <p>20 A. I'm not sure. I'm pretty sure within my group</p> <p>21 of friends, there had been a few people. Because they</p> <p>22 used to run a big blood donation at my high school,</p> <p>23 blood and plasma. But I cannot think of names.</p> <p>24 Q. Did you talk to anyone about what the process</p> <p>25 would be like before you went in?</p>	<p style="text-align: right;">Page 29</p> <p>1 Q. And why would you still like to donate?</p> <p>2 A. Well, firstly, because I'm a broke college</p> <p>3 student. But because I've seen the good it does, and</p> <p>4 I'd really like to -- I like to give back any way I</p> <p>5 can, and this is one of the ways I could.</p> <p>6 MS. WILLING: Let's take a quick break</p> <p>7 before we go on to other questions.</p> <p>8 (Break from 10:44 a.m. to 10:48 a.m.)</p> <p>9 Q. (BY MS. WILLING) Okay. Ms. Wolfe, let's talk</p> <p>10 about the day that you went into CSL. Like I said, I</p> <p>11 believe it was October 9, 2016; does that sound right?</p> <p>12 A. Yes.</p> <p>13 Q. Did you go in the morning, the afternoon?</p> <p>14 A. Early morning.</p> <p>15 Q. How early?</p> <p>16 A. Probably around 8:00 a.m. I had read you</p> <p>17 should get there when they open because lines got long.</p> <p>18 Q. So was 8:00 o'clock when they opened?</p> <p>19 A. I believe so, yeah.</p> <p>20 Q. And did anyone come with you?</p> <p>21 A. No, it was just me.</p> <p>22 Q. And Harley was there, as well?</p> <p>23 A. Yeah.</p> <p>24 Q. Do you drive, walk; how did you get there?</p> <p>25 A. I drive.</p>

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<p style="text-align: right;">Page 30</p> <p>1 Q. So what happened when you first got there?</p> <p>2 A. I walked in and hopped in line.</p> <p>3 Q. Was the line pretty long already?</p> <p>4 A. There were about six people in there, yeah.</p> <p>5 And there were already a lot of people in the waiting</p> <p>6 area too and being taken back in another line.</p> <p>7 Q. Do you remember about how many people were in</p> <p>8 the waiting room?</p> <p>9 A. Probably between five and ten.</p> <p>10 Q. And so what happened after you got in line?</p> <p>11 A. I waited in line until I got to the front, and</p> <p>12 then I gave her my -- my Social Security card. I think</p> <p>13 I gave her my lease because they needed to know where</p> <p>14 you lived. And my ID. And then I also -- I did have</p> <p>15 my letter from my doctor regarding Harley, just in</p> <p>16 case.</p> <p>17 Q. And what does that letter say?</p> <p>18 A. That I am a disabled individual under the ADA</p> <p>19 and require the use of a service dog to mitigate my</p> <p>20 disability.</p> <p>21 Q. Do --</p> <p>22 A. I --</p> <p>23 Q. Go ahead.</p> <p>24 A. I keep it on me for police and such.</p> <p>25 Q. Did the person at the front ask to see a</p>	<p style="text-align: right;">Page 32</p> <p>1 think the woman who came back to the small room was</p> <p>2 Ms. Juliana. And then asked me to step out and go talk</p> <p>3 to her in the other room.</p> <p>4 Q. So you think Juliana is the one that talked to</p> <p>5 you for a second and then brought you back to an exam</p> <p>6 room?</p> <p>7 A. Yeah. And then I'm -- she was the one I did</p> <p>8 have that discussion with in the exam room.</p> <p>9 Q. And so what was the discussion in the exam</p> <p>10 room?</p> <p>11 A. She asked why I had a service dog, why I</p> <p>12 needed him, what he did. And then she had -- I believe</p> <p>13 the MSR, she called it. And she was looking up</p> <p>14 guidelines regarding service animals. But she wasn't</p> <p>15 really able to find much of anything. So she looked up</p> <p>16 anxiety and went to the -- got on the computer and did</p> <p>17 an online thing.</p> <p>18 Q. So to you, it looked like she was trying to</p> <p>19 figure out what to do --</p> <p>20 A. Yes, ma'am.</p> <p>21 Q. -- about your situation?</p> <p>22 And did she ever come to a conclusion?</p> <p>23 A. Not while I was in the exam room. She tried</p> <p>24 to call their physician, who did not answer after</p> <p>25 several times. And then she attempted to call the</p>
<p style="text-align: right;">Page 31</p> <p>1 letter?</p> <p>2 A. Yeah. Yeah. And I -- it seemed like a gray</p> <p>3 area to me. I didn't know if she was allowed to ask</p> <p>4 for it, but I presented it because she asked for it.</p> <p>5 And I wasn't sure if she was not allowed to ask for it</p> <p>6 in this case.</p> <p>7 Q. And what happened after you talked to the</p> <p>8 front desk person?</p> <p>9 A. She had me step to the side so she could call</p> <p>10 someone and then started working with the person behind</p> <p>11 me in line. About -- when she handled I think a couple</p> <p>12 other people, maybe ten minutes, she came -- she asked</p> <p>13 me to come back to a -- you know those rooms where one</p> <p>14 door enters to one side and one door enters to the</p> <p>15 other and you have the medical desk in between?</p> <p>16 Q. Um-hmm.</p> <p>17 A. Back into one of those to wait for about five,</p> <p>18 six minutes to talk to someone. And I think she asked</p> <p>19 my name. Looked at my driver's license maybe. Then I</p> <p>20 had to wait five more minutes. And then she asked me</p> <p>21 to meet her outside in the hallway to go back into an</p> <p>22 examination room.</p> <p>23 Q. So by this point, had you just dealt with the</p> <p>24 same one individual, or were there two individuals?</p> <p>25 A. There were two, the front desk lady and then I</p>	<p style="text-align: right;">Page 33</p> <p>1 hotline they had and left a message for a doctor and</p> <p>2 told -- asked me or told me she would go ahead and let</p> <p>3 me go home, and then she'd give me a call later.</p> <p>4 Q. And so at that point, how long do you think</p> <p>5 you had been at the center?</p> <p>6 A. Maybe an hour. We did sit back in the exam</p> <p>7 room for a good bit.</p> <p>8 Q. By "good bit," was that maybe half of the</p> <p>9 time, or what do you think?</p> <p>10 A. Probably a little more than half. Probably 45</p> <p>11 minutes, because she was trying to get ahold of someone</p> <p>12 to answer her questions.</p> <p>13 Q. And what else do you remember from the time</p> <p>14 where you were sitting in the exam room talking to</p> <p>15 Juliana?</p> <p>16 A. Just general questions about -- she did ask</p> <p>17 whether I was on two medications, which I was not at</p> <p>18 the time. We discussed -- we talked about the anxiety</p> <p>19 a little. And she stated I didn't seem anxious.</p> <p>20 Because I asked her, "Do I seem really anxious?"</p> <p>21 And she said, "No, you seem really calm."</p> <p>22 And I had asked -- I asked if she thought</p> <p>23 I would be able to donate, and she said she wasn't</p> <p>24 sure, but she thought I might because my anxiety seemed</p> <p>25 under control.</p>

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34 to 37

<p style="text-align: right;">Page 34</p> <p>1 Q. Anything else from when you were at the 2 center? 3 A. Not that I can think of. 4 Q. So you said then she said that you could go 5 home? 6 A. Yeah. 7 Q. And so did you leave pretty much immediately 8 after that? 9 A. Yeah. I made sure she had my number and asked 10 her to go ahead and give me a call and told her if she 11 wouldn't mind having the doctor call me. But the 12 doctor never called me, but Ms. Juliana did later that 13 day. 14 Q. About how much later did Juliana call you? 15 A. It was a few hours. Yeah. 16 Q. And what do you remember from that 17 conversation? 18 A. That I was told I was being deferred and would 19 not be allowed to donate because my anxiety required 20 the use of a service animal. And I confirmed it was 21 because of the type of service animal, that they did 22 allow other service animals back for hearing impaired 23 or vision impaired. And just in general, I was being 24 deferred because I required a service animal for my 25 anxiety. And that if I did not require a service</p>	<p style="text-align: right;">Page 36</p> <p>1 A. Yes, ma'am. 2 Q. Was Juliana apologetic? 3 A. I guess like she would be to any other donor 4 who was rejected. 5 Q. Did they give you any other reason other than 6 just that you had the anxiety? 7 A. No, ma'am. Just that my anxiety required a 8 service dog. 9 Q. And did they explain why they don't let people 10 with severe anxiety donate? 11 A. No, ma'am, not that I recall. 12 Q. And you said that after Juliana called you, no 13 one else called you back; is that right? 14 A. Yes, ma'am. I was expecting the doctor to 15 call me maybe that Monday, but they never followed up. 16 It was just Juliana. 17 Q. And did you ever follow up with CSL? 18 A. No, I did not. I was quite anxious on the 19 whole issue, so... 20 Q. Were you afraid you'd have an attack if you 21 called or if you followed up with them? 22 A. I wasn't afraid of an anxiety attack, but 23 phone calls tend to make me a bit nervous. They're 24 more uncomfortable than anything. 25 Q. Were you nervous when you were at CSL?</p>
<p style="text-align: right;">Page 35</p> <p>1 animal anymore for my anxiety, I would be allowed to 2 donate. 3 Q. So she told you that if you ever got to the 4 point where your anxiety lessened to where you did not 5 need a service animal that you could come back and 6 donate? 7 A. Yes, ma'am. 8 Q. Did she tell you anything else? 9 A. Not that I can recall. 10 Q. So did you talk to anyone other than the front 11 desk person and Juliana when you were at CSL? 12 A. No, ma'am. 13 Q. Was Juliana rude to you at all? 14 A. No, ma'am. 15 Q. Did she mention -- did Juliana mention that 16 your anxiety might be a safety issue? 17 A. Not that I recall. 18 Q. Did she tell you that they were concerned that 19 you might have an anxiety attack on the donor floor? 20 A. Not that I recall. She didn't -- it -- she 21 didn't seem to think my anxiety was very bad, I think, 22 from her impression of me. 23 Q. So as you understand it, she didn't think the 24 anxiety was bad, but when she called the doctor, that's 25 who said that you could not donate; is that right?</p>	<p style="text-align: right;">Page 37</p> <p>1 A. Not until I was pulled back and they started 2 asking about my disability. But I figured that would 3 make anyone a little nervous. 4 Q. Do you get anxious if someone's asking you a 5 lot of questions about yourself? 6 A. It depends on the situation. It wasn't really 7 that they were asking me so many questions. But it's 8 that they singled me out and pulled me back. 9 Q. Were you aware that all donors get -- 10 eventually get pulled into an exam room for a physical 11 exam and a medical history questionnaire? 12 A. Yes. It was just that they did it because I 13 had a service dog. So it's like, "Okay, you have 14 glasses. Come back and talk to us." I just feel very 15 singled out at times. 16 Q. Did she tell you that she pulled you out of 17 line because she wanted to figure out what the answer 18 was before you had to wait? 19 A. Yeah, I believe so. But by that point, I had 20 already waited through the line, so... 21 Q. So what you said, you had already waited 22 through the line, but then she pulled you out of line? 23 A. When I got to the front of the line, she 24 pulled me to the side. 25 Q. So do you know what the step -- next step</p>



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38 to 41

<p style="text-align: right;">Page 38</p> <p>1 would have been if you had gone through the process?</p> <p>2 A. I'm not sure.</p> <p>3 Q. But you think that the process that as it</p> <p>4 happened to you was different than as it happened to</p> <p>5 other people?</p> <p>6 A. Yes, ma'am.</p> <p>7 Q. And how do you think it was -- other than the</p> <p>8 fact that you got deferred, how do you think that the</p> <p>9 process of finding out if you were going to be deferred</p> <p>10 or not was different?</p> <p>11 A. No one else was pulled out to the side and</p> <p>12 then asked immediately to go back. I believe others</p> <p>13 were given paperwork first, maybe questionnaires or</p> <p>14 something. I know they were not immediately pulled</p> <p>15 back into either of the rooms.</p> <p>16 Q. So other people had to go through a few more</p> <p>17 steps first?</p> <p>18 A. I believe so, yeah.</p> <p>19 Q. And what did you do once you got home from</p> <p>20 CSL?</p> <p>21 A. I talked with my boyfriend about what had</p> <p>22 happened, and then I talked to a couple of my groups.</p> <p>23 Q. Was that just to tell them what happened or to</p> <p>24 get advice, or what were you talking to them about?</p> <p>25 A. I was wondering if anyone else had had the</p>	<p style="text-align: right;">Page 40</p> <p>1 Q. And you said you've been too anxious to donate</p> <p>2 anywhere else, other than CSL; is that right?</p> <p>3 A. Yeah. It's -- I would have liked to have</p> <p>4 tried, but the energy to donate, just getting up the</p> <p>5 energy to go and to attempt to donate, gathering the</p> <p>6 documentation just to be turned away there is kind of</p> <p>7 not worth the energy at times as a full-time student</p> <p>8 and a full-time worker.</p> <p>9 Q. After you were deferred, did you learn</p> <p>10 anything more about the plasma donation process?</p> <p>11 A. Not really.</p> <p>12 Q. Do you understand that the plasma donation</p> <p>13 centers defer a lot of different people for a variety</p> <p>14 of medical reasons?</p> <p>15 A. Yeah.</p> <p>16 Q. Do you think it's fair that the plasma</p> <p>17 donation centers can decide who is able to donate and</p> <p>18 who is not able to donate?</p> <p>19 A. I'm not sure. I think to a certain degree, of</p> <p>20 course, the FDA regulations must be followed and in the</p> <p>21 interest of safety of others, yes. But I think they</p> <p>22 might be too broad with it or use old standards</p> <p>23 possibly.</p> <p>24 Q. If the doctors who work at CSL knew that</p> <p>25 donating plasma would hurt the person who was donating,</p>
<p style="text-align: right;">Page 39</p> <p>1 experience. I felt very -- I don't want to say</p> <p>2 "rejected," but in a way, and ostracized. And I wanted</p> <p>3 to know if anyone else had had the same experience. If</p> <p>4 they thought I should report it or something or just in</p> <p>5 general if -- what other people had done when faced</p> <p>6 with this.</p> <p>7 Q. And did you talk to them before you heard back</p> <p>8 from Juliana or after?</p> <p>9 A. I think it was after.</p> <p>10 Q. Would that be because before you heard back,</p> <p>11 you thought you still might be able to donate?</p> <p>12 A. Yeah.</p> <p>13 Q. You said you had had previously filed</p> <p>14 complaints with the DOJ. Did you do that in this case?</p> <p>15 A. Yes, ma'am. As far as I remember, yes.</p> <p>16 Q. Did you talk to any other people that had been</p> <p>17 deferred from the plasma donation process?</p> <p>18 A. No, ma'am.</p> <p>19 Q. Did you talk to anyone else who was not</p> <p>20 allowed to donate plasma?</p> <p>21 A. I believe a couple of the people who responded</p> <p>22 on my post had been told they couldn't donate. But I</p> <p>23 don't know if it was at CSL or not. I didn't directly</p> <p>24 talk to anyone at CSL or from CSL who had been</p> <p>25 deferred.</p>	<p style="text-align: right;">Page 41</p> <p>1 for example, if someone was pregnant and so donating</p> <p>2 plasma would harm them, do you think it's fair that</p> <p>3 they can turn away someone who's pregnant?</p> <p>4 A. Yes, ma'am.</p> <p>5 Q. So to some level, you think it's okay that CSL</p> <p>6 turns away people because donating could harm the</p> <p>7 donor?</p> <p>8 A. Yes, in certain cases.</p> <p>9 Q. But you think that you should be able to</p> <p>10 donate?</p> <p>11 A. Yes, ma'am.</p> <p>12 Q. Do you think you're qualified to donate?</p> <p>13 A. I believe so. I don't believe I would clearly</p> <p>14 be harmed by donating. I don't think there's a clear</p> <p>15 danger to me, enough to defer me. Because my anxiety</p> <p>16 is controlled. Even if Harley is in the lobby room, I</p> <p>17 could still donate in the back with no problem.</p> <p>18 Q. Do you know all of the different medical</p> <p>19 parameters for donating plasma?</p> <p>20 A. I know the generals.</p> <p>21 Q. But you never went through the whole medical</p> <p>22 exam, so you don't know, say, if your blood pressure</p> <p>23 was too high or your hematocrit was too low or --</p> <p>24 A. No, ma'am. Sorry.</p> <p>25 Q. It's okay. It happens.</p>



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42 to 45

<p style="text-align: right;">Page 42</p> <p>1 Could you see the donor floor from where you 2 were at the center? 3 A. Yes, ma'am, I believe so. 4 Q. Could you see how many beds there were? 5 A. I believe so. In the little open area, and it 6 was set up. You came in the front door. There's a 7 waiting room. The exam room's back this way 8 (indicating). The desk is here. And then there was a 9 long line. Then you could see the donor floor. And it 10 looked like -- I'm not sure how many, but I know I saw 11 some. 12 Q. Was there a chance that you would have an 13 anxiety attack when you were on a donor bed? 14 A. There's a slight possibility, but I don't 15 believe in that circumstance, as I'm comfortable in 16 medical areas. And I believe in medical areas, people 17 are more focused on themselves. And when you have a 18 giant needle in your arm, you're going to be a little 19 more internally focused than outwardly focused. 20 Q. Even if there's a lot of people walking 21 around? 22 A. Yeah. I've given blood before, and I've 23 always been comfortable with it. And I am -- I'm more 24 focused inward when I'm -- when in a medical setting. 25 Q. Do your migraines have any specific triggers</p>	<p style="text-align: right;">Page 44</p> <p>1 down when I ask him to. He doesn't really move around 2 much. He just stands up and stares at me and bumps me 3 with his nose occasionally. 4 Q. What happens if you get a panic attack 5 somewhere that you can't leave? 6 A. Then he'll do deep pressure therapy, and I can 7 sit through it. If I can leave during a bad one, I'd 8 prefer to because it does help me get through it 9 faster. But I can sit through them if they do occur. 10 Q. Can you sit through them even without the deep 11 pressure therapy? 12 A. If needed, yes. I will be exhausted the rest 13 of the day, however, but... 14 Q. So if you had a panic attack when you were 15 donating and you were on the bed, so he probably 16 couldn't get on top of you, you could just sit through 17 it? 18 A. Yes. If he were with me, I would also be able 19 to stim, feeling his fur. He's taught to keep my hand 20 on him if I'm panicky because my touch sensation is 21 heightened. So sometimes just repetitive petting 22 helps. So I trained him, if he's not up on me, he'll 23 keep my hand on him as a sort of distraction and 24 grounding mechanism. 25 Q. Is your pain sensation heightened when you</p>
<p style="text-align: right;">Page 43</p> <p>1 or do -- do those happen randomly? 2 A. They're random. 3 Q. And what about -- you said the chronic pain, 4 is that random or triggered? 5 A. It's random, but mostly triggered by stress. 6 Q. And how often do you get migraines? 7 A. It used to be a few times a week. But now 8 it's maybe once a month or twice a month. But 9 recently, it's been even less. So I've been reducing 10 my stress, working out more, and eating healthy. 11 Drinking a lot more water, too, so... 12 Q. So you were able to see in the donor room. 13 And the beds are a little bit elevated; could you see 14 that? 15 A. Yeah. 16 Q. If you had brought Harley back and you had had 17 a cortisol spike while you were donating, what do you 18 think he would have done? 19 A. He would have stood up and nosed me with his 20 nose. 21 Q. If he thought you were going to have a bad 22 panic attack, you said he will try to get you out of 23 the room. And you said he gets restless. What does he 24 do when he gets restless? 25 A. He basically just stands up and won't lie back</p>	<p style="text-align: right;">Page 45</p> <p>1 have panic attacks? 2 A. Not really. 3 Q. So if you have a panic attack, say, in a 4 classroom, and you don't leave, do you just sit there 5 and get very nervous and fidgety, or what else happens? 6 A. I get very nervous and fidgety. I tend to 7 tune out a little. So I'll miss what the professor is 8 saying sometimes. If I do sit through them, they last 9 longer. 10 Q. About how long? 11 A. Anywhere from 30 minutes to an hour. But as 12 soon as Harley starts helping, it reduces them to maybe 13 10 to 15 minutes, even less sometimes. 14 Q. So any other symptoms of an anxiety attack, 15 other than nervous fidgeting and tuning out? 16 A. My thoughts race sometimes. Sometimes, I'll 17 have a tightness in my chest. 18 Q. Anything else? 19 A. No, I think that's the gist. 20 Q. You said in your complaint that CSL's deferral 21 of you was not based on any valid reasons. Do you 22 still believe that? 23 A. I believe that, yes. 24 Q. And why do you believe that? 25 A. Because I believe my anxiety is controlled and</p>

Amy Wolfe  
July 07, 2017

50 to 53

<p style="text-align: right;">Page 50</p> <p>1 THE WITNESS: Sorry.</p> <p>2 Q. (BY MS. WILLING) So what are you hoping to</p> <p>3 get out of this lawsuit?</p> <p>4 A. I would like CSL to change their</p> <p>5 discriminatory policy so that others are not excluded</p> <p>6 from donating if they are -- if it is safe for them.</p> <p>7 And compensation -- com- -- sorry -- compensation for</p> <p>8 the mental -- I think, anguish is what it was called,</p> <p>9 that the interactions caused. And that's the simplest</p> <p>10 way I could put it.</p> <p>11 Q. So you experienced mental anguish from being</p> <p>12 deferred; is that right?</p> <p>13 A. Yeah.</p> <p>14 Q. Would you say the mental anguish was just from</p> <p>15 the deferral, or was it from also being asked questions</p> <p>16 about your anxiety?</p> <p>17 A. It was from both. It was from being deferred</p> <p>18 because of my service animal directly, and the --</p> <p>19 the -- yeah, the kind of out-of-nowhere personal</p> <p>20 questions about the disability and what he did and</p> <p>21 everything. She also asked how I got the disability,</p> <p>22 which was very sensitive at the time.</p> <p>23 Q. So did you think your medical history was not</p> <p>24 relevant to your ability to donate plasma?</p> <p>25 A. I thought it was relevant, but I don't think</p>	<p style="text-align: right;">Page 52</p> <p>1 With Kroger, I was taken over to the</p> <p>2 manager and -- by the security personnel who asked a</p> <p>3 bunch of questions and went to talk to the manager</p> <p>4 alone. But I was still allowed to finish shopping and</p> <p>5 everything once it was cleared up.</p> <p>6 This was the first instance of it</p> <p>7 actually -- basically, me being told I would not be</p> <p>8 served because I needed a service animal, and it</p> <p>9 definitely was not a fun experience. I had -- I did</p> <p>10 end up becoming quite depressed over it.</p> <p>11 Because the easiest way to describe it is</p> <p>12 like you have a birthmark, and -- and you go into a</p> <p>13 store, and they say, "Well, I can't serve you because</p> <p>14 you have a birthmark. Because it's so noticeable, I</p> <p>15 noticed it."</p> <p>16 It's -- how do I say that? It's an</p> <p>17 overarching con- -- consequence, if that makes sense.</p> <p>18 Basically, you start to question, am I going to be able</p> <p>19 to go anywhere without someone calling attention to my</p> <p>20 disability. I just want to be treated normally.</p> <p>21 Am I going to have to deal with being</p> <p>22 turned away constantly. How is this going to affect</p> <p>23 personal relationships, business relationships. How is</p> <p>24 this going to affect school. That might seem a bit</p> <p>25 dramatic, but when this is your daily reality, it's a</p>
<p style="text-align: right;">Page 51</p> <p>1 the anxiety was -- I think the anxiety was controlled</p> <p>2 well enough where it would not have been an issue. But</p> <p>3 that was never brought into question. It was just all</p> <p>4 or nothing, which I don't think was exactly</p> <p>5 appropriate.</p> <p>6 Q. So it's your position that the nurses at CSL</p> <p>7 should not be able to decide who can donate, that it's</p> <p>8 the donors that could -- should get to decide; is that</p> <p>9 right?</p> <p>10 A. I think it should be based, of course, on FDA</p> <p>11 standards. But they should be looked at more on a</p> <p>12 case by case than a broad overall. And I think they</p> <p>13 should focus on -- how do I say this? Sorry. I think</p> <p>14 it should be based on a case-by-case basis rather than</p> <p>15 stereotypical umbrella terms.</p> <p>16 Q. So you said you experienced mental anguish</p> <p>17 from the deferral; is that right?</p> <p>18 A. Yeah.</p> <p>19 Q. Can you describe or give me an example of that</p> <p>20 mental anguish?</p> <p>21 A. Yeah. I had been -- I had had access issues</p> <p>22 in the past before this, but they had always been</p> <p>23 resolved. Even if I had been yelled at by a manager,</p> <p>24 they apologized, and I had been able to finish what I</p> <p>25 had come to do.</p>	<p style="text-align: right;">Page 53</p> <p>1 constant.</p> <p>2 And in the past, I have debated having a</p> <p>3 service dog because of this. But that instance really</p> <p>4 made me question, though the pros did outweighs the</p> <p>5 cons. He's done so much to change my life, so much to</p> <p>6 help me. I wouldn't be able to leave my house without</p> <p>7 him most days.</p> <p>8 On my worst days, I wouldn't be able to</p> <p>9 get out of bed or eat or take care of myself. On my</p> <p>10 good days, I can leave him at home for a little bit and</p> <p>11 I'm okay. But I need other supports, and that's still</p> <p>12 barely getting by. It's -- it's MacGyvering it just</p> <p>13 enough to get by, but not enough to escape the harm</p> <p>14 that comes from it.</p> <p>15 I really did start to question was it</p> <p>16 worth -- like I just want to be a functioning member of</p> <p>17 society. I'm physically -- I was doing really great at</p> <p>18 the time. I was healthy. The mental disabilities were</p> <p>19 the main thing I was dealing with.</p> <p>20 And it just really hit home, someone</p> <p>21 could turn me away and just say no and kick me out and</p> <p>22 be like, I don't want to hear what you say. Like I</p> <p>23 don't care what the law says. I don't -- I see this,</p> <p>24 and I don't approve of it or something like that,</p> <p>25 and -- or I see this, and I don't believe you need it.</p>

KEY	DONOR	MEDICAL	DONOR	MEDICAL	DONOR	COMM	DATE	DATE	STMP
00D32AX	0001						20150407	04/07/2015	13:34:21
00D32AX	0002						20150103	04/07/2015	13:34:21
00D32AX	0003						20150102	04/07/2015	13:34:21
00D32AX	0004						20150102	04/07/2015	13:34:21
00D32AX	0005						20150102	04/07/2015	13:34:21
00D32AX	0006						20140205	04/07/2015	13:34:21
00D32AX	0007						20140122	04/07/2015	13:34:21
00D32AX	0008						20140120	04/07/2015	13:34:21
00D32AX	0009						20140120	04/07/2015	13:34:21
00D32AX	0010						20140115	04/07/2015	13:34:21
00D32AX	0011						20140115	04/07/2015	13:34:21
00D32AX	0012						20140112	04/07/2015	13:34:21
00D32AX	0013						20140112	04/07/2015	13:34:21
00D32AX	0014						20140112	04/07/2015	13:34:21
00D32AX	0015						20140112	04/07/2015	13:34:21
00D32AX	0016						20140112	04/07/2015	13:34:21

Called donor and left message. nb 4/7/2015

1/3/15-DONOR PR'D FOR THREATENING STAFF-TMB 1/3/15.

MGMT must speak to this donor prior to his next donation. MSA MM told donor he wo

uld be unable to donate due to using a cane and walking with a limp. He told her

that she "would regret this" and left. DT 01/02/2015

slight discoloration to left vp ok to donate mg 2/5/14

Donor bruise has healed, ok to donate. VUJ 1/22/14

DONOR RETURNED AND STILL HAS SOME BRUISING. TOLD HIM TO RETURN WHEN IT HAS

HEALED COMPLETELY. DONOR UNDERSTOOD. ET 1.20.14

donor has less 3in bruise to left vp. only uses left vp. not ok to donate

until resolved mg 1/15/14

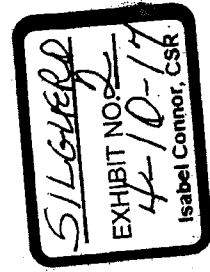
Review of MQ medical approvals complete. overdue PE granted mg 1/12/14

donor uses cane for support. donor states sometimes knees ache d/t body

weight. mg 1/12/14

donor is able to transfer on and off exam table and donation bed ok to

donate mg 1/12/14



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#### Instructions for Use

The following items are guidelines only. Individual cases must be evaluated on a case-by-case basis. Medical staff associates are to use their clinical judgment and discuss cases with the Center Medical Director/Center Physician when needed. The Medical Call Line is also available if the CMD/CP cannot be reached. The outcome of these discussions may warrant alternative decisions than those listed.

Additionally, when a donor relates a history of an otherwise disqualifying disorder that was present and resolved in the distant past, the donor may be acceptable after discussion with the CMD/CP or corporate MedOps. This does not apply to those labeled **Regulatory Requirement**.

Interpretation of guidelines: When a guideline reads "Acceptable if:" followed by one or more listed items, the recommendation is that (unless otherwise noted – e.g. "OR") all of the items must be met for the donor to be considered acceptable. If all conditions are not met, the recommendation is that the donor is not acceptable.

In those cases where regulatory requirements exist, these are noted in **Bold Type**. These requirements may not be altered and deviations are not permitted.

#### Medications

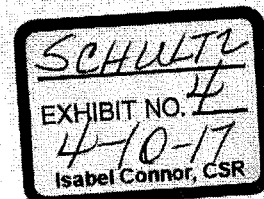
When donors admit to the use of medications that are unfamiliar to the Medical Staff, an internet search (e.g., Medline) must be conducted to determine category of medication and typical uses. Determine if the medication and reason for use are acceptable for donation. If uncertain contact your CMD/CP or the MedOps call line for assistance.

#### Open-Ended Questions

When interviewing a donor, it is imperative to ask open-ended questions to elicit the maximum amount of information.

Example: Do not say "Oh, you've got a bug bite". Instead ask "What is this? How did you get it? When did you get it?"

Example: MSA: "I see you marked yes to convulsions or epilepsy. Tell me about that. Were you diagnosed with epilepsy? What was the cause? When was your last convulsion? What medications were you on? Are you still taking medications? If not, when did you stop taking medications? Did you stop taking the medications at your doctor's direction?"



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**Documentation**

When a donor provides a history of a medical diagnosis, that specific diagnosis (not symptoms of the disease process) must be documented in the DRF, as well as any approvals needed for that specific diagnosis (if applicable). For example: donor admits to history of epilepsy and meets all criteria listed for acceptability to donate; sample documentation: "history of epilepsy, last seizure 20 years ago, no seizure medications for 15 years, ok to donate".

**Search the Document**

This document may be searched online for specific topics. To accomplish this, go to iNet -> Controlled Documents, open this document, click on the binoculars or click in the Search box (or go to Edit, Find). Type-in the word or phrase for which you are looking and click on Enter or the "Find Next" arrow, located next to the Search box. Click the "Find Next" arrow until all entries in the document with this word or phrase have been found (a message telling you that no more matches are found will appear).

**Basis of Conditions Guidelines**

The Conditions Guidelines have been developed to meet FDA and European Union regulatory requirements and to assure donor and plasma safety, as determined by corporate Medical Operations. A donor whose medical condition, disability or behavior conflicts with FDA, GHA or EU Regulations for the production of source plasma is to be deferred.

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Disabilities -  
See SOP for  
specific  
guidance

If ...	Then ...
Reasonable and safe accommodation can be made without disruption of center operations or contravention of manufacturing environment	Acceptable
Mental or behavioral	Acceptable if: <ul style="list-style-type: none"> <li>• Able to give informed consent</li> <li>• Does not violate center standards</li> </ul>
Resulting from unacceptable medical conditions	Permanent deferral
On unacceptable medications	Permanent deferral
Unsteady gait, falling, dizziness	Defer
Scale access	Acceptable if: Able to stand on scale without assistance Exception: Donors in wheelchairs may alternately provide a doctor's note stating the weight as specified in <b>CTR02121, Impaired Donors</b> and <b>CTR04021W-ah, Initiating Medical Screening and Donor Weight</b>
Transfer to donor bed	Acceptable if: Able to safely transfer to and from donor bed without assistance

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#### Health Care Provider (HCP) Letters

If ...	Then ...
After interviewing the donor, additional information is required	<ul style="list-style-type: none"> <li>• Defer donor until HCP letter is received and reviewed for donor's suitability OR</li> <li>• Schedule the donor to return when the CMD/CP is available to meet with the donor OR</li> <li>• Contact the CMD/CP to inquire whether a HCP letter is required</li> </ul>
Previously requested HCP letter	Donor acceptable without HCP letter if: Request for letter is no longer applicable (ie, surgery as a small child, condition no longer present)
Conditions applied by HCP (e.g., may donate once a week)	Defer donor until conditions do not need to be applied
Question regarding medication(s)	Pharmacy printout is acceptable, in lieu of a HCP letter
Repeat HCP letters	If a donor has provided an HCP letter for a specific reason, it is not mandatory to repeat the HCP letter request for the same condition, if recurrent. May consider time-based deferral.

#### Procedures and Surgeries

The following are general surgical guidelines. More information is found under specific procedures

If ...	Then ...
Major surgery (e.g., laparotomy, thoracotomy, large joint replacements)	Acceptable if: At least 4 months since procedure
Minor surgery (e.g., laparoscopic surgeries, small joint surgeries)	Acceptable if: At least 4 weeks since procedure
Biopsy	See <i>Biopsy</i>
Tooth extraction	See <i>Dental Procedures</i>
Procedures using flexible scopes	<b>Regulatory Requirement</b> 4 month deferral due to method of instrument sterilization

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Procedures using rigid scopes	Due to method of sterilization used, deferral beyond procedure deferral is not required
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### Whole Blood Criteria

When different from Normal Source Plasma (NSP) criteria, whole blood criteria can be found at the end of this document.

### Medical Topics, Alphabetical Listing

Abscess Drainage	If ...		Then ...	
	Closed		Acceptable if: <ul style="list-style-type: none"><li>• Antibiotic criteria are met</li><li>• Redness and warmth resolved</li></ul>	
Accutane® (isotretinoin)	Regulatory Requirement			
	Defer 30 days after last dose			
Acne	Acceptable. Antibiotics to treat acne are not cause for deferral			
Acne Rosacea	Acceptable. Antibiotics to treat acne are not cause for deferral			
Acoustic Neuroma	Acceptable if at least 4 weeks since surgery or gamma knife treatment			
Actinic Keratosis	If ...		Then ...	
	Recently removed		Defer until healed	
	All others		Acceptable	
Acupuncture	If performed by...		Then ...	
	Licensed (to perform acupuncture) practitioner		Acceptable	
	Non-licensed practitioner		Defer at least 12 months since treatment	
Addison's Disease	Permanent deferral			
Adenoidectomy	See <i>ENT Surgeries</i>			
Adrenal	If ...		Then ...	
	Cyst, Benign		Acceptable	
	Hyperplasia, Congenital		Permanent deferral	
	Insufficiency		Permanent deferral	
Allergies	If ...		Then ...	
	Allergic to adhesives (e.g., Band-Aid®, tape)		Acceptable if: <ul style="list-style-type: none"><li>• Alternative wrap is used in center</li></ul>	

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		Not acceptable to leave center with the following in place: <ul style="list-style-type: none"><li>• Scotch tape</li><li>• Masking tape</li><li>• Other types of non-medical tape</li></ul>							
	Anaphylaxis	<table><tr><th>If . . .</th><th>Then . . .</th></tr><tr><td>Known source, substance not used in center (e.g., seafood)</td><td>Acceptable if not to substance used in center</td></tr><tr><td>Known source, substance used in center (e.g., Betadine®)</td><td rowspan="2">Permanent deferral</td></tr><tr><td>Unknown source</td></tr></table>	If . . .	Then . . .	Known source, substance not used in center (e.g., seafood)	Acceptable if not to substance used in center	Known source, substance used in center (e.g., Betadine®)	Permanent deferral	Unknown source
If . . .	Then . . .								
Known source, substance not used in center (e.g., seafood)	Acceptable if not to substance used in center								
Known source, substance used in center (e.g., Betadine®)	Permanent deferral								
Unknown source									
	Allergic to Betadine®, shellfish, iodine	Acceptable BUT always use alternate scrub							
	Allergic to Citrus fruits	Acceptable							
	Contact dermatitis	See <b>Contact Dermatitis</b>							
	Allergic to Contrast agent (X-rays, etc), iodine	Acceptable BUT always use alternate scrub							
	Allergic to Foods	Generally acceptable. If allergic to seafood, always use alternate scrub							
	Allergic to Latex	<table><tr><th>If ...</th><th>Then ...</th></tr><tr><td>Anaphylaxis</td><td rowspan="2">Permanent deferral</td></tr><tr><td>Respiratory symptoms</td></tr><tr><td>Mild symptoms</td><td>Acceptable</td></tr></table>	If ...	Then ...	Anaphylaxis	Permanent deferral	Respiratory symptoms	Mild symptoms	Acceptable
If ...	Then ...								
Anaphylaxis	Permanent deferral								
Respiratory symptoms									
Mild symptoms	Acceptable								
	Allergic to Nickel	Permanent deferral if: <ul style="list-style-type: none"><li>• Severe OR</li><li>• Repeatedly develops rash at VP site</li></ul>							
Allergic Rhinitis	Acceptable, w/ or w/o nasal sprays (including steroid sprays) if symptoms controlled								

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Allergy Treatments							
	If ...	Then ...					
	Shots	Acceptable if at least 1 day since last injection					
	Allergy testing	<table><tr><td>If ...</td><td>Then ...</td></tr><tr><td>Skin testing</td><td>Acceptable if:<ul style="list-style-type: none"><li>• At least 1 day since testing</li><li>• Wheals resolved</li></ul></td></tr><tr><td>Blood testing</td><td>Acceptable</td></tr></table>	If ...	Then ...	Skin testing	Acceptable if: <ul style="list-style-type: none"><li>• At least 1 day since testing</li><li>• Wheals resolved</li></ul>	Blood testing
If ...	Then ...						
Skin testing	Acceptable if: <ul style="list-style-type: none"><li>• At least 1 day since testing</li><li>• Wheals resolved</li></ul>						
Blood testing	Acceptable						
Alzheimer's Disease	Permanent deferral						
Amnesia	See also <i>Head Trauma</i>						
	If ...	Then ...					
	Short term following trauma	Defer at least 7 days after injury; assess for resolution					
	All others	Assess case-by-case, including the donor's ability to understand and recall the risks and other information in the informed consent					
Amoebic Dysentery	Acceptable if: <ul style="list-style-type: none"><li>• At least 7 days since medication complete</li><li>• Donor well</li></ul>						
Amputation	Acceptable if: <ul style="list-style-type: none"><li>• No disqualifying underlying condition</li><li>• Surgical conditions met - See <i>Procedures and Surgeries</i></li><li>• Able to safely transfer to and from donor bed</li></ul>						
Amyotrophic Lateral Sclerosis (ALS / Lou Gehrig's Disease)	Permanent deferral						
Anabolic Steroids							
	If ...	Then ...					
	Injected and not prescribed by physician (e.g., body building)	Permanent deferral					
	Prescribed by physician to stimulate growth	Acceptable					
Anemia	If ...	Then ...					
	Iron deficiency	Acceptable if all acceptance criteria are met					
	Recurrent low hematocrit	May need: <ul style="list-style-type: none"><li>• HCP letter and/or</li></ul>					

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		• Temporary deferral	
	Pernicious anemia	Acceptable if successfully treated	
	B12 injections	Acceptable if prescribed by HCP	
	Oral iron supplements	Acceptable	
	Iron injections	Defer <ul style="list-style-type: none"><li>• At least 8 weeks since last injection AND</li><li>• HCP letter is required</li></ul>	
Aneurysm Repair	See <i>Vascular Surgery</i>		
Angina Pectoris	Permanent deferral		
Angioplasty	If ...		Then ...
	Cardiac		Permanent deferral
	Peripheral		See <i>Vascular Surgery</i>
Anisocoria	Acceptable if: <ul style="list-style-type: none"><li>• Congenital or</li><li>• Related to trauma or surgery</li></ul>		
Ankylosing spondylitis	Acceptable: <ul style="list-style-type: none"><li>• If able to transfer safely</li><li>• Not on disqualifying medications, such as TNF inhibitors (e.g., Enbrel®)</li></ul>		
Anorexia	See <i>Eating Disorders</i>		
Antecubital Area	If ...		Then ...
	Bruising		Acceptable when resolving. <b>Note:</b> Donors with extensive bruising on one arm may not donate from the other arm until bruising is resolving (fading to yellow).
	Foreign body		Acceptable if not within 3 inches of venipuncture site
	Scarring	If ...	Then ...
		Surgical due to vascular repair or nerve release	Unacceptable to use affected arm – other arm may be acceptable
		Tattoo removal	Permanent deferral
		Cigarette burns along a vein	
Antibiotics	Always assess reason for use		
	If ...		Then ...
			Acceptable if:

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	IV or IM	<ul style="list-style-type: none"><li>• At least 4 weeks since last dose AND</li><li>• Donor well</li></ul>	
	Oral, for acne or UTI prophylaxis	Acceptable	
	Oral, for illness or infection	Acceptable if: <ul style="list-style-type: none"><li>• At least 1 day since last dose AND</li><li>• Donor well</li></ul>	
	Topical, for minor skin lesions	Acceptable	
	Topical, including drops, active infection	Acceptable if <ul style="list-style-type: none"><li>• At least 1 day since last dose AND</li><li>• Donor well</li></ul>	
	Topical, including drops, prophylaxis	Acceptable	
Anti-Coagulation Therapies	If ...		Then ...
	Any oral anticoagulants alone or in combination with Heparin or tPA  See <i>Pulmonary Embolism</i>	And ...	Then ...
		<ul style="list-style-type: none"><li>• Used for single episode DVT AND</li><li>• 12 months or more since last dose</li></ul>	Acceptable
		<ul style="list-style-type: none"><li>• Low dose and used as surgical prophylaxis</li></ul>	Acceptable if at least 14 days since last dose
	<ul style="list-style-type: none"><li>• Used as chronic prophylaxis OR</li><li>• DVT occurred while on medication</li></ul>	Permanent deferral	
	Heparin	Acceptable if: <ul style="list-style-type: none"><li>• Surgical prophylaxis AND</li><li>• Medication stopped AND</li><li>• Asymptomatic AND</li><li>• Deferral period from surgery has expired</li></ul> Permanent deferral if: <ul style="list-style-type: none"><li>• Chronic medical condition</li><li>• Ongoing use</li></ul>	



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	Low molecular weight heparin	See <b>Heparin</b>
	Plavix®, Ticlid®and similar anti-platelet medications	Minimum of 14 day deferral from cessation of medication. Assess condition. Permanent deferral for atherosclerotic vascular disease
Anti-Diuretic Medications (e.g., DDAVP®)		
	If Used For...	Then ...
	Nocturnal enuresis (bedwetting)	Acceptable when medication discontinued
	Diabetes insipidus	Permanent deferral
	Hemophilia von Willebrand's disease	
Anti-Emetic	Acceptable when: • Medication discontinued AND • Donor well	
Anti-Fungal		
	If ...	Then ...
	Oral or topical for skin, nail, or vaginal infections	Acceptable
	Systemic infection	<ul style="list-style-type: none"><li>• IV - defer until 4 months after completion of treatment</li><li>• Oral – defer until 2 weeks after completion of treatment</li></ul>
Antihistamine / Decongestant		
	If Used For...	Then ...
	Allergy symptoms	Acceptable if symptoms controlled
	Motion sickness	
	Itching	Acceptable if no open skin lesions
Anti-Phospholipid Syndrome		
	If...	Then...
	Identified in association with pregnancy complication, now resolved	Acceptable
	Identified with other systemic disease	Permanent deferral
Anti-Spasmodic Medication	Acceptable if no disqualifying underlying condition	
Anti-Viral		
	If Used For...	Then ...
	Flu	See <b>Influenza</b>
	Herpes, genital or oral	See <b>Herpes</b>

<b>CSL Plasma</b>	SOP No.: MA02016	Rev.: 05	Page 11 of 71
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	All others	Assess carefully, including HCP letter stating reason for use
<b>Anxiety Disorders</b>	<b>If ...</b>	<b>Then ...</b>
	Severe, frequent	Permanent deferral
	Induced by plasma center environment	Permanent deferral
	Requires more than 2 medications daily for control of symptoms or service animal required	Defer until need for medications (or animal) decreased
	Currently with symptoms	Temporary deferral until resolved
<b>Aortic valve, bicuspid or stenotic</b>	Permanent deferral	
<b>Aplastic anemia</b>	Permanent deferral	
<b>Appendectomy</b>	<b>If ...</b>	<b>Then ...</b>
	Laparoscopic	Defer at least 4 weeks since procedure
	Laparotomy (open)	Defer at least 8 weeks since procedure
<b>Arnold-Chiari Malformation</b>	Acceptable if: • At least 5 years since uncomplicated surgical correction • No disqualifying grafts	
<b>Arrhythmia</b>	If disqualifying underlying cardiac disease, permanent deferral.	
	Use the following table if no disqualifying underlying cardiac disease:	
	<b>If ...</b>	<b>Then ...</b>
	Ablation	Acceptable, if: • 2 years or more since ablation and • On no more than 2 medications to control rhythm
	Atrial, chronic (Examples: recurrent paroxysmal atrial tachycardia, atrial fibrillation)	Permanent deferral
	Atrial tachycardia, isolated (e.g., pregnancy related)	Defer at least 1 year since episode
	Bradycardia	Refer to <b>CTR04021W-a)</b>
	Bundle branch block	Acceptable if pulse within acceptable range and PVC criteria met and no history of myocardial infarction (heart attack)
	On medications other than calcium channel blockers or beta blockers to control/prevent arrhythmia	Permanent deferral

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	Pacemaker	Permanent deferral
	Premature atrial/ventricular contractions (PACs/PVCs) – known history	Acceptable if 5 or fewer per minute Temporary deferral if 6-7 per minute (apply medical deferral until 5 or fewer) Permanent deferral if 8 or more per minute
	Skipped/extra beats	If no known history, consider HCP letter. If known history, see appropriate section
	Supraventricular tachycardia (SVT)	Acceptable if: • No occurrence in past year and • On no more than 2 medications to control rhythm
	Tachycardia, recurrent (not ventricular)	Consider time-based deferral
	Ventricular fibrillation Ventricular tachycardia	Permanent deferral
	Wolff-Parkinson-White (WPW) Syndrome, treated successfully	See <b>Arrhythmia, Ablation</b>
	Wolff-Parkinson-White (WPW) Syndrome, untreated or treated with medication	Permanent deferral
Arteriosclerosis	Permanent deferral	
Arteriovenous Malformation	See <b>Cerebral Aneurysm / AVM</b>	



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Donor/Unit Information

ABORN

Donor # 00032AX  
Last Name SILGUERO  
Suffix  
First Name MARK (E)  
Sex Male  
Date of Birth 01/11/2014  
Donation # 1567

Don. 01/11/2014  
Date 04/11/2014 Center 0803 Photo B. Route Archived  
BP

Results (All-1)  
Separation (All-2)  
Comments (All-2)  
Deferrals (All-3) - A  
Questionnaire (All-3)  
Tests History (All-3)

Letters Printed (All-A)  
Demographics (All-C)

Donations / Year: Whole Blood:000 Plasma:000 Apheresis:000 Red Cells:000

Don.	01/11/2014
60303670285	04/08/2014
60303652868	04/02/2014
60303956432	03/12/2014
60303979901	02/12/2014
60303991345	02/05/2014
60304034854	01/30/2014
60303912677	01/24/2014
60303810380	01/12/2014
60303885987	01/11/2014
60301523290	12/18/2013

01/11/2014

SCHULTZ  
EXHIBIT NO. 5  
4-10-17  
Isabel Connor, CSR

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CSL-Silguero0000001

## Medical Questionnaire by Date

Visit Date Range: 11/30/2011 12:00:00 AM - 4/12/2014 12:00:00 AM  
eProgesa Direct

Donor Number	00D32AX
Donor Name	SILGUERO, MARK

Visit Date	Center Name	Center Code or Incomplete Donation	Question Order	Question Code	Question	Answer	Employee Name
11/30/2011	CORPUS CHRISTI 603 ZCTX	603	01	JL	(REVISED) In the past 7 days, have you donated plasma or tried to donate plasma at a center other than a CSL center?;	No	Chavez, Jana
11/30/2011	CORPUS CHRISTI 603 ZCTX	603	02	1A	Are you feeling well and healthy today?;	Yes	Chavez, Jana
11/30/2011	CORPUS CHRISTI 603 ZCTX	603	03	1B	Have you read the High Risk Poster?;	Yes	Chavez, Jana
11/30/2011	CORPUS CHRISTI 603 ZCTX	603	04	1C	Are you in any of the INCREASED Risk groups described in the High Risk Poster?;	No	Chavez, Jana

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## Medical Questionnaire by Date

Visit Date Range: 11/30/2011 12:00:00 AM - 4/12/2014 12:00:00 AM

aProgesa Direct

Visit Date	Center Name	Center Code or Incomplete Donation	Question Order	Question Code	Question	Answer	Employee Name
04/11/2014	CORPUS CHRISTI 603 ZCTX	Incomplete Donation	34	VA	Donor may continue the screening process?:	Yes	Maldonado, Sandra
04/11/2014	CORPUS CHRISTI 603 ZCTX	Incomplete Donation	35	R4	Defer donor for presence of fingernail dye?:	No	Maldonado, Sandra
04/11/2014	CORPUS CHRISTI 603 ZCTX	Incomplete Donation	36	R2	Was fingernail dye applied per SOP (if applicable)?:	Yes	Maldonado, Sandra
04/11/2014	CORPUS CHRISTI 603 ZCTX	Incomplete Donation	37	3B	Weight:	369	Maldonado, Sandra

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<b>CSL Plasma</b>	SOP No.: MA02016	Rev.: 08	Page 1 of 73
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#### Instructions for Use

The following items are guidelines only. Individual cases must be evaluated on a case-by-case basis. Medical staff associates are to use their clinical judgment and discuss cases with the Center Medical Director/Center Physician when needed. The Medical Call Line is also available if the CMD/CP cannot be reached. The outcome of these discussions may warrant alternative decisions than those listed.

Additionally, when a donor relates a history of an otherwise disqualifying disorder that was present and resolved in the distant past, the donor may be acceptable after discussion with the CMD/CP or corporate MedOps. This does not apply to those labeled **Regulatory Requirement**.

Interpretation of guidelines: When a guideline reads "Acceptable if:" followed by one or more listed items, the recommendation is that (unless otherwise noted – e.g. "OR") all of the items must be met for the donor to be considered acceptable. If all conditions are not met, the recommendation is that the donor is not acceptable.

In those cases where regulatory requirements exist, these are noted in **Bold Type**. These requirements may not be altered and deviations are not permitted.

#### Medications

When donors admit to the use of medications that are unfamiliar to the Medical Staff, an internet search (e.g., Medline) must be conducted to determine category of medication and typical uses. Determine if the medication and reason for use are acceptable for donation. If uncertain contact your CMD/CP or the MedOps call line for assistance.

**Medication List** entries – follow the deferral listed on the form

#### Open-Ended Questions

When interviewing a donor, it is imperative to ask open-ended questions to elicit the maximum amount of information.

Example: Do not say "Oh, you've got a bug bite". Instead ask "What is this? How did you get it? When did you get it?"

Example: MSA: "I see you marked yes to convulsions or epilepsy. Tell me about that. Were you diagnosed with epilepsy? What was the cause? When was your last convulsion? What medications were you on? Are you still taking medications? If not, when did you stop taking medications? Did you stop taking the medications at your doctor's direction?"



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<b>CSL Plasma</b>	SOP No.: MA02016	Rev.: 08	Page 3 of 73
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Disabilities -  
See **CTR02121**,  
**Impaired Donors**  
for specific  
guidance

If ...	Then ...
Reasonable and safe accommodation can be made without disruption of center operations or contravention of manufacturing environment	Acceptable
Mental or behavioral	Acceptable if: <ul style="list-style-type: none"> <li>• Able to give informed consent</li> <li>• Does not violate center standards</li> </ul>
Service animals	If particular situation is not addressed in <b>CTR02121</b> , contact your MedOps resource
Resulting from unacceptable medical conditions	Permanent deferral
On unacceptable medications	Permanent deferral
Unsteady gait, falling, dizziness	Defer
Scale access	Acceptable if: Able to stand on scale without assistance <b>Exception:</b> Donors in wheelchairs may alternately provide a doctor's note stating the weight as specified in <b>CTR02121, Impaired Donors</b> and <b>CTR04021W-ah, Initiating Medical Screening and Donor Weight</b>
Transfer to donor bed	Acceptable if: Able to safely transfer to and from donor bed without assistance

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	instrument disinfection
Procedures using rigid scopes (e.g., arthroscopy)	Deferral beyond procedure deferral is not required due to sterilization methods

#### Whole Blood Criteria

When different from Normal Source Plasma (NSP) criteria, whole blood criteria can be found at the end of this document.

#### Medical Topics, Alphabetical Listing

Abscess Drainage		
	If ...	Then ...
	Closed	Acceptable if: <ul style="list-style-type: none"><li>• Antibiotic criteria are met</li><li>• Redness and warmth resolved</li></ul>
Acne	Acceptable. Antibiotics to treat acne are not cause for deferral	
Acne Rosacea	Acceptable. Antibiotics to treat acne are not cause for deferral	
Acoustic Neuroma	Acceptable if at least 4 weeks since surgery or gamma knife treatment	
Actinic Keratosis		
	If ...	Then ...
	Recently removed	Defer until healed
	All others	Acceptable
Acupuncture		
	If performed by...	Then ...
	Licensed (to perform acupuncture) practitioner	Acceptable
	Non-licensed practitioner	Defer at least 12 months since treatment
Addison's Disease	Permanent deferral	
Adenoidectomy	See <i>ENT Surgeries</i>	
Adrenal		
	If ...	Then ...
	Cyst, Benign	Acceptable
	Hyperplasia, Congenital	Permanent deferral
	Insufficiency	Permanent deferral
Allergies		
	If ...	Then ...
	Allergic to adhesives (e.g., Band-Aid®, tape)	Acceptable if: <ul style="list-style-type: none"><li>• Alternative dressing is used in center</li></ul> Not acceptable to leave center with



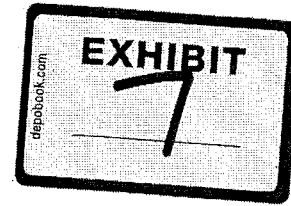
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Allergy Treatments	If ...		Then ...	
	Shots		Acceptable if at least 1 day since last injection	
	Allergy testing			
			If ...	Then ...
		Skin testing	Acceptable if: <ul style="list-style-type: none"><li>• At least 1 day since testing</li><li>• No open sores</li></ul>	
		Blood testing	Acceptable	
Alzheimer's Disease	Permanent deferral			
Amnesia	See also <i>Head Trauma</i>			
	If ...		Then ...	
	Due to trauma		Defer at least 7 days after injury; assess for resolution	
	All others		Assess case-by-case, including the donor's ability to understand and recall the risks and other information in the informed consent	
Amoebic Dysentery	Acceptable if: <ul style="list-style-type: none"><li>• At least 7 days since medication complete</li><li>• Donor well</li></ul>			
Amputation	Acceptable if: <ul style="list-style-type: none"><li>• No disqualifying underlying condition</li><li>• Surgical conditions met - See <i>Procedures and Surgeries</i></li><li>• Able to safely transfer to and from donor bed</li></ul>			
Amyotrophic Lateral Sclerosis (ALS / Lou Gehrig's Disease)	Permanent deferral			
Anabolic Steroids	If ...		Then ...	
	Injected and not prescribed by physician (e.g., body building)		Permanent deferral	
	Prescribed by physician to stimulate growth		Acceptable	
Anemia	If ...		Then ...	
	Iron deficiency		Acceptable if all screening criteria are met	
	Recurrent low hematocrit		May need: <ul style="list-style-type: none"><li>• HCP letter and/or</li></ul>	

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Title: Medical Staff Reference - Conditions Guidelines			Effective Date: 23 MAY 2016

Antibiotics	Always assess reason for use		
	If ...	Then ...	
	IV or IM	Acceptable if: <ul style="list-style-type: none"><li>• At least 4 weeks since last dose AND</li><li>• Donor well</li></ul>	
	Oral, for acne or UTI prophylaxis	Acceptable	
	Oral, for illness or infection	Acceptable if: <ul style="list-style-type: none"><li>• At least 1 day since last dose AND</li><li>• Donor well</li></ul>	
	Topical, for minor skin lesions	Acceptable	
	Topical, including drops, active infection	Acceptable if <ul style="list-style-type: none"><li>• At least 1 day since last dose AND</li><li>• Donor well</li></ul>	
	Topical, including drops, prophylaxis	Acceptable	
Anti-Coagulation Therapies	If ...	Then ...	
	Any oral anticoagulants alone or in combination with Heparin or tPA  See <i>Pulmonary Embolism</i>	And ...	Then ...
		<ul style="list-style-type: none"><li>• Used for single episode DVT AND</li><li>• 12 months or more since last dose</li></ul>	Acceptable
		<ul style="list-style-type: none"><li>• Low dose and used as surgical prophylaxis</li></ul>	Acceptable if at least 14 days since last dose
		<ul style="list-style-type: none"><li>• Used as chronic prophylaxis</li></ul>	Permanent deferral
	Heparin	Acceptable if: <ul style="list-style-type: none"><li>• Surgical prophylaxis AND</li><li>• Medication stopped AND</li><li>• Asymptomatic AND</li><li>• Deferral period from surgery has expired</li></ul>	





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Donor/Unit Information

ABO/Rh

Donor #  
Last Name  
Suffix  
First Name  
Sex  
Date of Birth  
Donation #

8062H01U  
WOLFE  
ARMY (C)  
Male  
07/01/1966  
✓

Photo Not Available

Results (Alt-1)  
Separation (Alt-2)  
Comments (Alt-3)  
Deferrals (Alt-4) - A  
Demographics (Alt-5)

Tests History (Alt-6)

Donations / Year Whole Blood: 500 Plasma: 100 Apheresis: 000 Red Cells: 000

Don

CSL-Silguero000324

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**Medical Communication Form****Detail Report**

Reference: 1531069

Form: 01431496268

**General Part**

Center Code 0143  
 Creation User ID C155174A  
 Creation User Name JULIANA SANCHEZ  
 Creation Date 10/09/2016

**Donor Information**

Donor Number 00G2K0U  
 Donor Name AMY WOLFE

**Detail Information****Medical Communication**

Purpose of Communication \* Other  
 Purpose of Communication Comments DONOR CAME IN WITH SERVICE DOG. DONOR HAD HISTORY OF SEVER ANXIETY AND PTSD NOT ON ANY PRESCRIBED MEDICATIONS.  
 Name of Person Contacted DR. NELSON  
 Discussion Outcome Defer Donor - Temporary  
 Discussion Comments DR.NELSON ADVISED THAT DONOR IS NOT ALLOWED TO DONATE UNTIL SERVICE DOG IS NO LONGER REQUIRED OR IS ON LESS THAN 2 MEDICATIONS.

**e-Signature for Detail Information:**

JULIANA SANCHEZ 11/10/2016 01:36 PM

**Physician Information**

Has the communication been reviewed? Yes

**e-Signature for Physician Information:**

RABIA SHAFI 11/16/2016 11:40 AM

**Quality Assurance Review**

QA Review Comments NA

**e-Signature for Quality Assurance Review:**

SHAWNTRALA STEPHENS 11/16/2016 09:11 PM

**Medical Notes**

eProgesa Data

Center Name	Donor Number	Donor Name	Medical Note Timestamp Date	Donor Medical Note	Employee Name
HOUSTON CENTER 0143	00G2K0U	WOLFE, AMY	10/09/2016	DONOR STATED SHE HAS ANXIETY AND PTSD. TAKES NO MEDICATION CURRENTLY FOR EITHER DIAGNOSIS. DONOR HAS HAD PTSD FOR 3 YEARS AND ANXIETY SINCE CHILHOOD. DONOR REQUIRES SERVICE DOG FOR ANXIETY. CONTACTED DR. NELSON AND DR. SHAFI ON CLEARANCE BEHALF. WAITING FOR RESPONSE.	SANCHEZ, JULIANA
HOUSTON CENTER 0143	00G2K0U	WOLFE, AMY	10/09/2016	SPOKE TO MED OPS. DONOR IS NOT SUITABLE FOR DONATION DUE TO SEVER ANXIETY REQUIRING SERVICE DOG. DONOR IS ELIGIBLE TO DONATE PER PHYSICIAN GUIDELINES IF SERVICE DOG IS NO LONGER NECESARRY OR ON LESS THAN 2 MEDICATIONS FOR ANXIETY/PTSD.	SANCHEZ, JULIANA

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Last Report Refresh Date: January 19, 2017

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CSL-Silguero000327

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
CORPUS CHRISTI DIVISION

MARK SILGUERO,

Plaintiff,

AMY WOLFE,

Intervenor Plaintiff,

V.

CSL PLASMA INC.,

Defendant.

CIVIL ACTION NO. 2:16-CV-00361

**DECLARATION OF JOHN NELSON, M.D., PH.D.**

I, John Nelson, declare the following under penalty of perjury pursuant to 28 U.S.C.

§ 1746:

1. I am a Divisional Medical Director with CSL Plasma.
2. Donors who have fallen at CSL centers have fractured their arms and legs, suffered head trauma with lacerations and concussions, as well as fractured or lost teeth.
3. A donor with an unsteady gait presents a risk of falling after donation.
4. A significantly overweight donor with an unsteady gait presents a higher risk of injuring CSL staff if the donor was to fall and the staff attempted to catch the donor, or attempted to help the donor up after falling.

Executed on August 10, 2017 at Las Vegas, Nevada.

John Nelson, M.D., Ph.D.

30836875.1